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Discrepancies in Self-Reported Financial Conflicts-of-Interest Disclosures by Physicians: Systematic Review and Meta-Analysis

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Abstract

Background: There is a high prevalence of financial conflicts-of-interest (COI) between clinicians and industry. Many physicians have been reported to omit, or incompletely disclose relevant COI, even in situations in which guidelines require this disclosure. We performed a systematic review and meta-analysis to examine the completeness of self-reported financial COI disclosures by physicians, and identify the factors associated with non-disclosure.

Methods: Medline (1946 – April 2020), Embase (1947 – April 2020), and PsycInfo (1806 – April 2020) searches were supplemented with material identified in the references and in citing articles. Data were independently abstracted by two of the authors and disagreements were resolved by a third author.

Results: 40 studies were included. There was a high prevalence (66%-93%) of discrepancies in the reporting of financial COI amongst physicians, across a range of academic settings and clinical specialties. Most undisclosed COI were those related to expenses such as food and beverage, or travel and lodging. Undisclosed payments accounted for 33% of the total payments received. While the most common explanation for failure to disclose was perceived irrelevance, a median of 45% of non-disclosed payments arose from industry sources that were directly or indirectly involved in the published or presented work. A smaller monetary amount was the most commonly reported predictor of nondisclosure.

Conclusions: Physicians self-report of financial COI are highly discrepant with objective data sources reporting payments from industry. Stronger policies are required by journal editors to reduce reliance on physician self-reporting of financial COI.

Strengths and limitations of this study

- The study characterized discrepancies in self-reported payments across multiple settings and disciplines.
- The results were stratified across different levels in order to provide more accurate estimates of discrepant reporting.
- The population and methodologies used for assessment of conflicts of interest are not the same across studies.
- Many of the objective data sources used in this study relied on disclosures by industry, which may have inconsistencies.
- The study is largely limited to physicians in the United States and may not be generalizable to other countries.

Background

Financial conflicts-of-interest (COI) between physicians and industry commonly occur, and are a longstanding area of public concern.[1, 2] They occur in situations where a person has a moral obligation to exercise judgment in another's service and, at the same time, an interest tending to interfere with the proper exercise of judgment in that relationship. Under this definition "Judgment" refers to intelligent activity requiring more than mechanical rule following; "interest" refers to personal financial benefit, family interest or any special influence or loyalty which could undermine the performance of one's duty to exercise one's judgment objectively." [3] Financial COI have the potential to undermine the integrity of medical research, education, and practice.[3, 4, 5] Considerable evidence indicates that financial COI may influence the conduct and reporting of research, increase the likelihood of research outcomes favoring the sponsor (usually the pharmaceutical or device industry).[6, 7] Additionally, financial COI may be associated with inappropriate prescribing patterns.[8]

Financial COI occur in situations in which there is transfer of payment from industry to physicians. This is independent of whether these payments are disclosed. The Institute of Medicine, a US non-profit organization which is independent government and which provides policy recommendations for public health and science, asserts that disclosures of conflicts of interest protect the integrity of professional judgment and preserve the public trust in physicians.[9] As such, over the past decade, many academic institutions and medical journals have adopted guidelines which guide disclosures of financial COI in a putative effort to increase transparency and encourage critical appraisal of research findings.

While there has emerged credible criticism that disclosure is not a solution to the management of COI,[10, 11] financial COI disclosures have become a quintessential part of conducting and publishing research, delivering academic presentations and educating medical students at this time. Complicating the issue is that disclosure of financial COIs relies almost entirely on self-reporting by those benefitting from financial gain. There has traditionally been no means of verification of the correlation between payments received, and disclosure. Indeed many physicians have been reported to omit, or incompletely disclose relevant COI, even in situations in which guidelines require this disclosure,[2, 12-15] resulting in incorrect information provided to those reading, interpreting, or using the data reported. The extent of and factors associated with this under-reporting of financial COI by physicians may be less well studied than warranted by this important issue. To date, there has not been a systematic search of the literature on the discrepancies between actual and disclosed financial COI. Our study aims to systematically examine the completeness of self-reported financial COI disclosures by physicians, and identify the factors associated with non-disclosure.

Methods

This systematic review was conducted according to the standards and guidelines established by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) and the fourth edition of the Joanna Briggs Institute Reviewer's Manual.[16, 17] Methods of the analysis and inclusion criteria were specified in advance and documented. Our protocol is publicly available (<https://osf.io/fzhd7>).

Eligibility Criteria

We included studies that sought to examine discrepancies between financial COI which were reported by physicians, and the objective data which documented payments from industry to the physicians. We considered a discrepancy to be present if data provided information about relevant financial support that was not reported by the physicians themselves. We examined only original, peer-reviewed literature in the English language. Articles were excluded if they did not focus on physicians, did not assess COI involving payments from the pharmaceutical (or device manufacturing) industry, or if they did not have available an objective comparator. We considered objective payment data to be any data that was not reported by physicians themselves. We reviewed studies that focused on disclosures in any setting, such as research publications, clinical practice guidelines, academic presentations, or conference committees. Published conference posters and abstracts were not eligible for inclusion.

Information Sources

We consulted a University of Toronto research librarian to help develop the search strategy. We searched Ovid MEDLINE (1946 – April 2020), Ovid EMBASE (1947 – April 2020), and PsycInfo (1806 – April 2020) using a combination of both MESH subject headings (exploded) and key words. Subject-specific search terms adapted from previously published systematic reviews on financial COI (“conflict of interest”, “financial support”, and “funding”) were combined with a filter to retrieve studies related to physicians.[18] The search strategy is included in the Appendix. In addition, we reviewed the references of included papers and searched for studies that have cited these papers using SCOPUS.

Study Selection

Study selection was completed in duplicate by two independent, parallel reviewers (AK, XL) using title, abstract and full-text screening. Disagreements between reviewers were resolved independently by a blinded third reviewer (CT). Covidence was used for both data management and screening.

Data Collection

To further refine extraction categories we developed, *a priori*, a data extraction sheet, and pilot-tested it on ten randomly-selected studies we had included. Data were extracted in duplicate by two independent, parallel reviewers (CT, XL). Disagreements were resolved by discussion between the two reviewers and subsequent consultation with a third author (AK).

From each study, we extracted the clinical focus, study design, primary objective, sources of data collection, time period during, how COI were defined number and monetary amount of total COI, number and monetary amount of undisclosed COI, number of relevant undisclosed COI, types of undisclosed COI, factors associated with undisclosed COI, reasons for non-disclosure, and association of nondisclosure with positive study outcomes.

We assessed the risk of bias of each included study using a modified version of the Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence data. The risk of bias assessment was done in duplicate by two independent, parallel reviewers (AK, XL). Disagreements were resolved by discussion between the two reviewers and subsequent consultation with a third author (CT).

Data Synthesis

The included studies were described and summarized by qualitative synthesis. We also conducted a meta-analysis of the studies which reported the data necessary to compute the proportion of payments discrepant and the amount of funds discrepant.

Statistical Analyses and Outcomes

Our primary outcome was the proportion of COI which was discrepant: that is, the proportion in which objective documentation of funding had not been self-reported. Our secondary outcome was the proportion of funds discrepant: that is the amount of funds (US dollars) which had not been self-reported. Disclosures that were reported by physicians, but not reported by the objective data source, were not considered to be discrepancies in this study.

Data were stratified into four groups according to whether they described discrepancies among authorships, authors, articles, or payments. Refer to table 1 below to better understand how we use these terms. In each case, the proportion of COI identified as discrepant between self-reporting and objective was defined as the number undisclosed COI over the total number of COI.

Table 1. Definitions of groups used to stratify data.

Group	Definition	Example
Authorship	One instance of disclosure by one individual. One authorship may involve multiple transactions.	Sorting by authorship can involve identifying any discrepancies in COI reporting by one author in a single published work.
Author	A unique individual who can have more than one authorship. An author may be involved in multiple authorships.	Sorting by author can involve identifying any discrepancies in COI reporting by one author among a number of publications.
Article	A group of individuals with authorships for a single published work	Sorting by article involves identifying any discrepancies in COI reporting by any author of a single published work.
Payment	A single transaction between industry and authors.	Sorting by payment involves identifying any discrepancies in COI reporting by one individual for a single transaction.

Each payment was treated as equal regardless of the amount of funding or the amount discrepant. The proportion of funds that was identified as discrepant between self-reporting and objective data

was defined as the amount of funding not disclosed as a proportion of the funds recorded in the payment database. The proportion of COI identified as discrepant between self-reporting and objective data and the proportion of funds identified as discrepant between self-reporting and objective data were pooled in the meta-analysis and analyzed using a random-effects model. The I^2 statistic was used to measure heterogeneity between studies and $p<0.05$ was considered statistically significant. Statistical analysis was performed using MedCalc Statistical Software v19.2.6.[19]

Results

Search Results

Figure 1 illustrates the PRISMA flow diagram. Searches and other data sources provided a total of 8460 citations. After removing duplicates, 5845 studies remained. Of these, we discarded 5781 studies after reviewing the abstracts which indicated the papers did not meet the inclusion criteria. One additional study was discarded because the full text of the study was not available. We assessed the full text of the remaining 63 citations. We identified a total of 40 studies for inclusion in the systematic review, 12 of which were identified by searching reference lists and citing articles. Inter-rater reliability for study screening for titles/abstract and full-text screening was 99.5% and 91.2% respectively. The authors were in substantial agreement or better with a calculated Kappa of 0.77 and 0.81 respectively.

Characteristics of Included Studies

Table 2 summarizes the characteristics of the 40 studies included in this analysis. All studies had a cross-sectional design. Thirty-eight studies were conducted in the United States and two in Denmark.[20, 21] Six studies assessed disclosures from academic meetings[12, 14, 22, 23, 24, 25], ten assessed disclosures in clinical practice guidelines[21, 26, 27, 28, 29, 30, 31, 32, 33, 34], 22 assessed those in other publications[13, 15, 20, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54], and one assessed those in both an academic meeting and publications.[51] All studies examined self-reported disclosures by physician authors or presenters of academic work; three studies also reported disclosures by conference organizers.[12, 23, 24] Most studies examined disclosures of physicians conducting work within a common discipline; four examined disclosures of physicians across a variety of disciplines.[13, 20, 37, 39] Disclosures in surgical disciplines were most commonly investigated; eight studies focused on disclosures of physicians working in orthopedic surgery[12, 14, 38, 40, 43, 46, 47, 54], three of those working in plastic surgery[15, 42, 51], two of those working in otolaryngology[23, 29], two of those working in urology[32, 53], and three of those working in other surgical specialties.[24, 45, 48] Aside from one which used data from the United States Department of Justice investigations,[37] all studies used industry-reported payment data as the objective comparison; of these 39 studies reliant upon industry-reported payment data, 30 examined data from the Centers for Medicare and Medicaid Services’ Open Payments Database (OPD)[13, 15, 23, 24, 25, 27, 28, 29, 30, 31, 32, 33, 34, 35, 38, 39, 40, 41, 42, 43, 44, 45, 47, 48, 49, 50, 51, 53, 54, 55], two studies used the ProPublica’s Dollars for Docs database[25, 36], two studies used both of these sources[23, 52], two studies used the Danish Health and Medicines Authority’s public disclosure list[20, 21], and three studies referenced the web pages of device manufacturers.[12, 14, 46] All included studies examined

different data sets except two [12, 46] both of which examined the same data set involving five manufacturers of total hip and knee prosthesis in 2007. Most studies examined COI involving relatively recent financial relationships; one study[37] examined relationships dating back to 1999. Two studies[49, 50] did not specify the time period studied.

Proportion of COI discrepant

As above the included studies examined COI involving articles, authors, disclosure statements, or payments. The majority of studies defined discrepancies as one or more undisclosed COI, but some studies used alternative definitions. Three studies considered a discrepancy to occur only when all COI were inaccurately disclosed by an author.[36, 47, 54]

Figure 2 summarizes the studies that examined the accuracy of self-reported financial COI. The pooled proportion of articles with a discrepancy was 81% (95% Confidence Interval (CI): 72%-89%). The pooled proportion of authors with a discrepancy was 66% (95% CI: 48%-78%). The pooled proportion of disclosure statements containing a discrepancy was 93% (95% CI, 79-100%). The pooled proportion of payments in which self-reports were discrepant from objective data was 79% (95% CI, 67-89). Heterogeneity of the data among studies was high at every level examined $I^2=94-99\%$. We observed no trends in discrepancy rates over time.

Table 2. Characteristics of included studies.

Author Year; Country	Study Design	Focus of Research	Self- Disclosure Source	Objective Data Source	Time of Payments
Ahmed 2018[22]; United States	Cross- sectional	Radiation- oncology	Authors of presentations at academic meeting	OPD	2013-2015
Alhamoud 2016[26]; United States	Cross- sectional	Cardiology	Authors of CPGs	DFD	2009-2012
Andreatos 2017[33]; United States	Cross- sectional	Various disciplines	Authors of CPGs	OPD	2013-2014
Bansal 2020[34]; United States	Cross- sectional	Gastroenterol ogy	Authors of CPGs	OPD	2013-2017
Bellomo 2020[36]; United States	Cross- sectional	Vascular	Authors of publications	DFD	2013-2016

Bindslev 2013[21]; Denmark	Cross-sectional	Various disciplines	Authors of CPGs	Danish Health and Medicines Authority disclosure list	2007-2012
Boddapati 2018[35]; United States	Cross-sectional	Sports medicine	Authors of publications	OPD	2014-2015
Boyll 2019[51]; United States	Cross-sectional	Plastic surgery	Authors of publications	OPD	2013-2016
Buerba 2013[14]; United States	Cross-sectional	Spine surgery	Authors of presentations at academic meeting	Company web pages	2010
Carlisle 2018[32]; United States	Cross-sectional	Urology	Authors of CPGs	OPD	2012-2014
Checketts 2017[31]; United States	Cross-sectional	Dermatology	Authors of CPGs	OPD	2013-2015
Cherla 2017[49]; United States	Cross-sectional	Pulmonology, hematology, orthopedics, cardiac surgery, otorhinolaryngology	Authors of publications	OPD	NR
Cherla 2018a[48]; United States	Cross-sectional	Surgery	Authors of publications	OPD	2012-2016
Cherla 2018b[50]; United States	Cross-sectional	Ventral hernia	Authors of publications	OPD	NR
Chimonas 2011[46]; United States	Cross-sectional	Orthopedics	Authors of publications	Company web pages	2017
Chopra	Cross-	Various	Authors of	OPD and	2013-2015

2020[52]; United States	sectional	disciplines	publications	DFD	
Combs 2019[30]; United States	Cross- sectional	Various disciplines	Authors of CPGs	OPD	2014-2017
Desai 2019[23]; United States	Cross- sectional	ENT	Authors of presentations at academic meeting	OPD and DFD	2013-2015
Dudum 2019[27]; United States	Cross- sectional	Cardiology	Authors of CPGs	OPD	2013-2017
Fu 2018[38]; United States	Cross- sectional	Orthopedic surgery	Authors of publications	OPD	2014-2015
Garrett-Mayer 2020[55]; United States	Cross- sectional	Oncology	Authors of presentations at academic meeting and publications	OPD	2016-2017
Horn 2018[29]; United States	Cross- sectional	Otolaryngolo gy	Authors of CPGs	OPD	2013-2016
Hughes 2019[54]; United States	Cross- sectional	Orthopedic surgery/sports medicine	Authors of presentations at academic meeting	OPD	2015
Janney 2019[47]; United States	Cross- sectional	Orthopedic surgery	Authors of publications	OPD	2013-2016
Jimbo 2019[53]; United States	Cross- sectional	Urology	Authors of publications	OPD	2013-2016
Kesselheim 2012[37]; United States	Cross- sectional	Various disciplines	Authors of publications	United States Department of Justice investigations	1999-2007
Lois 2019[25];	Cross-	Gastroenterol	Authors of	OPD	2017

United States	sectional	ogy	presentations at academic meeting		
Lopez 2018[15]; United States	Cross- sectional	Plastic surgery	Authors of publications	OPD	2013
Luce 2017[42]; United States	Cross- sectional	Plastic surgery	Authors of publications	OPD	2015
Norris 2012[13]; United States	Cross- sectional	Various disciplines	Authors of publications	DFD	2009-2010
Okike 2009[12]; United States	Cross- sectional	Orthopedic surgery	Authors of presentations at academic meeting	Company web pages	2007
Olavarria 2017[41]; United States	Cross- sectional	Ventral hernias	Authors of publications	OPD	2012-2014
Patel 2018[45]; United States	Cross- sectional	Robotic surgery	Authors of publications	OPD	2013-2014
Rasmussen 2015[20]; Denmark	Cross- sectional	Various disciplines	Authors of publications	Danish Health and Medicines Authority's public disclosure list	2010-2013
Ross 2020[40]; United States	Cross- sectional	Hand surgery	Authors of publications	OPD	2014-2016
Saleh 2019[28]; United States	Cross- sectional	Oncology	Authors of CPGs	OPD	2013-2017
Somerson 2020[43]; United States	Cross- sectional	Orthopedic surgery	Authors of publications	OPD	2015-2016

Tau 2019[39]; United States	Cross-sectional	Various disciplines	Authors of publications	OPD	2013-2015
Thompson 2016[24]; United States	Cross-sectional	Obstetrics/Gynecology	Authors of presentations at academic meeting	OPD	2014
Yee 2015[44]; United States	Cross-sectional	Ophthalmology	Authors of publications	OPD	2013

Abbreviations: CPG: Clinical Practice Guideline; OPD: Dollars For Docs (ProPublica); Open Payments Database (Centers for Medicare and Medicaid Services)

Relevance of discrepant COI

Nine studies reported the proportion of relevant discrepancies. Discrepancies were reported as being considered relevant if the payments provided was directly, or indirectly, related to the topic of the presentation, clinical practice guidelines, or another publication. Because only nine studies reported these data, and each had examined discrepancies at a different level, we elected to not pool this outcome. The proportion of relevant discrepancies ranges from 6% to 99%. The median proportion of relevant discrepancies is 45%. There is considerable heterogeneity across studies.

Proportion of funds (of the total funds reported) that were discrepantly reported

Nine studies reported the proportion of total amounts which were discrepantly reported (Figure 3). The pooled proportion of total payment amounts which were discrepant was 33%. Heterogeneity between studies was high $I^2=100\%$.

Types of COI that were discrepantly reported

Specific types of financial COI were reported as undisclosed in nine studies. These were similar across studies.[22, 27, 28, 31, 34 35, 38, 43, 55] The most common category of undisclosed COI was general payments. According to the payment databases, general payments include food and beverage, travel and lodging, consulting, royalties and licenses, non-consulting services (including serving as faculty or speaker at an event other than continuing education), payments for education, speaker and faculty fees, and honoraria.[27, 34, 35, 38, 43, 55] Within this category, food and beverage were identified by three studies as among the most frequently undisclosed.[38, 43, 55] Two studies identified travel and lodging[38, 55], two identified consulting and speaking[22, 27], and one identified non-consulting services (including serving as faculty or speaker at an event other than continuing education) as the most commonly undisclosed.[27] Two studies identified research payments as the most commonly undisclosed[22, 28], and another two studies identified them as commonly undisclosed.[34, 35]

Factors associated with discrepant reporting

A total of 15 out of 40 studies reported factors that are associated with discrepant reporting.[12, 14, 15, 22, 26, 33, 34, 35, 37, 40, 45, 46, 47, 49, 51] We conducted a qualitative synthesis of these factors. Table 3 summarizes the results of each study reporting factors that were associated with discrepant reporting of financial COIs. We organized factors into four categories: factors related to author characteristics (e.g., academic affiliation), payment characteristics (e.g., amount of the payment from industry), article characteristics (e.g., level/hierarchy of evidence, such as systematic review versus commentary), and journal characteristics (e.g., impact factor). Of these, author and payment were the most commonly reported factors that were associated with discrepant reporting.

Three studies examined the influence of any author’s gender in discrepant reporting.[22, 34, 35] There were contrasting results regarding the outcomes. Two studies reported that male gender was more associated with discrepant reporting of COI;[22, 34] one study reported that females were more likely to have discrepancies in the reporting of COI.[35] Multivariable regression analysis by Ahmed (2018) reported no association with author gender.[22] Six studies examined whether the position of an author on a scientific article influenced discrepant reporting.[34, 35, 37, 40, 46, 51] The data concerning author position was conflicting. Some studies found that prominent (first, last, or sole) authors were associated with discrepant reporting, while other studies found that other (middle) authors were associated with discrepant reporting. Two studies reported no association across authorship positions.[34, 37]

Other author-related factors include an affiliation with an academic institution, the physician specialty, and physician role at an academic meeting (e.g., organizer vs attendee). Two studies identified the influence of author affiliations on undisclosed payment;[15, 34] both reported authors with academic affiliation were significantly more likely to have undisclosed payments compared with authors who were not identified as having academic affiliations. One study reported that physician’s roles are associated with reporting behavior.[12] At one academic meeting, physicians who did not serve as board members or committee members at the annual meeting were less likely to disclose. Physicians who were not symposium presenters or instructional-course lecturers were also less likely to disclose. Four studies reported the associations between physician specialty and discrepant reporting.[33, 37, 45, 49] Three of these studies found a positive association[33, 45, 49]; one found no difference among specialties[37]. Patel (2018) reported that general surgeons were more likely to have discrepant reporting than those in other surgical specialties.[45] Cherla (2017) found that manuscripts related to hematology exhibited the highest discrepant reporting, while manuscripts related to otolaryngology were associated with the lowest rates.[49] Andreatos (2017) reported that authors of guidelines in general medicine, orthopedics, trauma, pulmonology, gastroenterology, and radiology had significantly higher rates of discrepant reporting than did authors of guidelines in other specialties.[33]

Six studies reported on the association of the value of payments that were not disclosed.[12, 14, 15, 26, 33, 35] Five found that authors who received smaller total payments or individual payments of lesser value were associated with discrepant reporting [12, 14, 15, 26, 35] Studies differed in what was reported to be considered “significant” amounts, from \$500[15], \$10,000[12, 26], \$100,000[12, 14], to \$500,000.[35] The sixth study was the only one to report no statistically significant association between discrepant reporting and the value of the payments involved.[33]

Five studies commented on other payment-related factors.[12, 15, 33, 35, 46] One study found that payments made to a group or organization were more likely to be undisclosed when compared to payments made to an individual physician.[12] Additionally, when payments did not include an in-kind component they were less likely to be reported.[12] Payments that were provided but were unrelated to the topic of a presentation or article in which the authors failed to disclose were more likely to be undisclosed when compared to directly and/or indirectly related payments.[12, 15, 46] However, not all payment types were equally likely to be unreported. “General payments” were more likely to be incompletely or inaccurately reported than “research payments”.[33]

Three studies commented on article-level factors associated with discrepancies.[35, 37, 45] One study found that when stratified by the level of evidence, authors of papers of higher levels of evidence (level of evidence ≥ 1) were significantly more likely to have discrepancies than those authors of papers of lower levels of evidence.[35] Likewise, commentaries were significantly less likely to have adequate disclosure compared to studies with original data.[37] Another study found that there was no difference between comparative (observational studies, randomized controlled studies or meta-analyses/systematic reviews) and non-comparative studies (case series, technique description or editorials/comments).[45] Additionally, article citation index per year since publication was not associated with adequacy of disclosure.[37]

Three studies described the association of journal characteristics with discrepant reporting.[37, 45, 46] Two studies found no statistically significant association with journal impact factor.[37, 45] Moreover, one study found that the accuracy of disclosures did not vary with the strength of journals’ disclosure policies, and there was no association between a journal’s endorsement of specific International Committee of Medical Journal Editors (ICMJE) policy recommendations, and discrepant reporting.[46]

Table 3. Results of studies investigating factors associated with discrepant reporting.

Study	Factors Evaluated	Significant Results
Ahmed 2018[22]	At least one disclosure* Duration of presentation Sex* Word count Year of presentation Words per second*	On univariable analysis, having at least one disclosure (OR, 2.62; 95% CI, 1.02-5.24) and male sex (OR, 3.76; 95% CI, 1.45-12.8) were associated with having a discrepancy. On multivariable regression, only the number of words per second was correlated to having a discrepancy (OR, 1.08; 95% CI, 1.01-1.80).
Alhamoud 2016[26]	Payment amount*	Payments $\geq \$10,000$ were 2.8 times more likely to be reported than modest or no payments (P=0.001).
Andreatos 2017[33]	Specialty* Type of payment* Total payment value	Authors of general medicine (P=0.02), orthopedics/ trauma (P=0.01), pulmonology (P=0.02), gastroenterology (P=0.02), and radiology (P=0.03) guidelines had significantly

		less accurate COI disclosures compared to other specialties. Authors were significantly less likely to inaccurately report “research payments” compared to “general payments” (75.5% vs 87.3%; P=0.02).
Bansal 2020[34]	Sex* Academic affiliation* Authorship order	Male authors (odds ratio, 2.23; 95% confidence interval, 1.47-3.39) and academically affiliated authors (odds ratio, 8.87;95% confidence interval, 5.57-14.13) were significantly more likely to have undeclared payments (P<0.001).
Boddapati 2018[35]	Payment amount* Authorship order* Sex* Level of evidence* Type of payment*	Authors with total payments >\$500,000 were less likely to be discrepant than those earning <\$10,000 (16.1% vs 85.3%; P<0.001). First authors had a lower percentage of payment values with discrepancy versus middle authors (13.8% vs 31.9%; P=0.001). Men had a lower percentage of payment values with discrepancy as compared with women (22.3% vs 95.3%; P<0.001). The discrepancy rate was lowest in the level of evidence 1 subgroup as compared with the other groups, such as level of evidence 2 (75.0% vs 90.3%; P=0.013). Authors were least discrepant in general payments compared to research and ownership payments (17.2% vs 32.7% vs 47.5%; P<0.001).
Boyll 2019[51]	Authorship order*	A middle author is less likely to have discrepancies than the first or last author (OR, 3.593; 95% CI, 1.211-10.657; P=0.0212).
Buerba 2013[14]	Payment amount*	Those who received payments <\$100,000 from Medtronic were more likely to have discrepancies in their disclosures than those who received payments >\$100,000 (P=0.009).
Cherla 2017[49]	Specialty*	Between the medical and surgical published literature, the discordance rate for manuscripts differed significantly (71.5% vs 60.7%; P=0.01). Hematology manuscripts exhibited the highest incomplete disclosure rate while Otorhinolaryngology manuscripts showed the lowest (75.0% vs 42.0%; P<0.001).
Chimonas 2011[46]	Authorship order* Payment relatedness*	First, sole, or senior authors were more likely to disclose than middle authors (54% vs 32%;

	Journal policy	P=0.03). Articles related to company payments were more likely to disclose compared to unrelated payments (50% vs 11%; P=0.04).
Janney 2019[47]	Year of publication	N/A
Kesselheim 2012[37]	Type of article* Specialty Authorship order Journal impact factor Article citation index	The researchers found that commentaries were significantly less likely to have adequate disclosure compared to articles reporting studies or trials (OR 0.10; 95% CI 0.02-0.67; P=0.02).
Lopez 2018[15]	Academic affiliation* Payment relatedness* Payment amount*	Nonacademic authors were 6.25 times more likely to disclose COI compared with authors with an academic affiliation (P<0.0001). Authors who received \$500 or more in transactions of value were 9.09 times more likely to disclose COI compared with authors who received less than \$200 (P<0.0001). Authors whose COI was related to the topic of their article were 2.75 times more likely to disclose conflicts of interest compared with authors whose COI was unrelated to the topic of their article (P<0.0001).
Okike 2009[12]	Payment amount* Payment made to an individual physician* Payment with in-kind component* Physician role* Payment relatedness*	Payments were more likely to have been disclosed if they exceeded \$10,000 than if they did not (64.4% vs 42.9%; P<0.001), were directed toward an individual physician rather than a company or organization (78.1% vs 45.9%; P=0.04), or included an in-kind component (79.0% vs 46.3%; P=0.002). Members of the board of directors or annual-meeting committees were more likely to disclose payments than others (86.0% vs 69.1%; P=0.009), and so were symposium presenters or instructional-course lecturers (87.0 vs 58.4%; P<0.001). Directly related payments were more likely to be disclosed than unrelated payments (79.3% vs 49.2%; P=0.008).
Patel 2018[45]	Study type Impact factor Specialty*	“Other” surgical subspecialties (including Cardiothoracic Surgery, Head and Neck, Neurosurgery, Vascular Surgery) were less likely to have discrepancies than general surgery (OR 0.61; 95% CI, 0.38 – 1.00; P=0.01).

Ross 2020[40]	Authorship order*	Authors listed last on a paper were found to have significantly more undeclared payments than first and middle authors (77% vs 47% vs 51%; P<0.0001).
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*Factor was significantly associated with nondisclosure
Abbreviations: COI: conflicts-of-interest; CI: confidence interval; OR: odds ratio

Reported explanation for discrepant reporting of fCOI

One study investigated *explanations* for non-disclosure by administering a survey to physicians who had not fully disclosed COI in the final program of an annual meeting.[12] with a response rate of 39.6% (36 / 91). The most common explanations for nondisclosure were that payment were considered unrelated to the topic of the presentation (39%; 14 of 36), or that disclosure requirements were misunderstood (14%; 5 of 36). Other explanations include that the payment was disclosed, but mistakenly omitted from the annual-meeting program (11%; 4 of 36), that the disclosure process was handled by a co-author who failed to communicate disclosure requirements (8%; 3 of 36), or that the payment was unintentionally omitted from the disclosure statement (6%; 2 of 36). Another 3% (1 of 36) reported that the payment from industry was not large enough to be disclosed.

Relationship between undisclosed COI and study outcomes

Data concerning the association unreported COI and the outcome of the research was reported by three studies, but the results are conflicting.[45, 48, 50] One study found that studies with discrepancies between declared COI and actual COI were more likely to report positive outcomes when compared to those that had no discrepancies, even after adjusting for impact factor, surgical specialty, and study type (OR 3.21, 95%CI 1.81 – 5.70, P < 0.0001).[45] However, two studies reported that authors with any COI, regardless of whether disclosed or not, were significantly more likely to report positive outcomes.[48, 50] In fact, in one of these studies, manuscripts in which authors fully disclosed all COI had a higher odds of providing a favorable impression of the discussed product (12.4, 95% confidence interval 4.4–35.4, p<0.001).[48]

Risk of bias assessment

Table 3 depicts the risk of bias assessments of the 40 included studies. Several studies did not use a wide-enough sample frame to address the study’s target population. For example, some studies had a target population of all physicians but their sample frame only included a single speciality. However, our review included a variety of specialities in order to draw inferences about physicians in general. Another possible source for bias is that included studies seldom performed a sample size calculation, as all were observational and exploratory. All studies had a low risk of bias overall.

Table 4. Risk of bias assessment of included studies using a modified Joanna Briggs Institute Critical Appraisal Checklist for studies reporting prevalence data.

Study	Checklist Item*							
	1	2	3	4	5	6	7	8
Ahmed 2018[22]								
Alhamoud 2016[26]								
Andreatos 2017[33]								
Bansal 2020[34]								
Bellomo 2020[36]								
Bindslev 2013[21]								
Boddapati 2018[35]								
Boyll 2019[51]								
Buerba 2013[14]								
Carlisle 2018[32]								
Checketts 2017[31]								
Cherla 2017[49]								
Cherla 2018a[48]								
Cherla 2018b[50]								
Chimonas 2011[46]								
Chopra 2020[52]								
Combs 2019[30]								

Desai 2019[23]								
Dudum 2019[27]								
Fu 2018[38]								
Garrett-Mayer 2020[55]								
Horn 2018[29]								
Hughes 2019[54]								
Janney 2019[47]								
Jimbo 2019[53]								
Kesselheim 2012[37]								
Lois 2019[25]								
Lopez 2018[15]; United States								
Luce 2017[42]; United States								
Norris 2012[13]								
Okike 2009[12]								
Olavarria 2017[41]								
Patel 2018[45]								
Rasmussen 2015[20]								
Ross 2020[40]								
Saleh 2019[28]								

Somerson 2020[43]								
Tau 2019[39]								
Thompson 2016[24]								
Yee 2015[44]								

*Checklist Item:

1. Was the sample frame appropriate to address the target population?
2. Were study participants sampled in an appropriate way?
3. Was the sample size adequate?
4. Were the study subjects and the setting described in detail?
5. Was the data analysis conducted with sufficient coverage of the identified sample?
6. Were valid methods used for the identification of the condition?
7. Was the condition measured in a standard, reliable way for all participants?
8. Was there appropriate statistical analysis?

Discussion

Statement of principal findings

Our review identified 40 cross-sectional studies which examined the accuracy of self-reporting of financial COI by physicians. The evidence examined indicates a high prevalence of discrepancies in the reporting of financial COI among physicians across a range of academic settings and clinical specialties. Most undisclosed COI were those related to expenses such as food and beverage, or travel and lodging. Undisclosed payments accounted for 33% (95% confidence interval 12–58%) of the total payments received. The most common explanation for failure to disclose COI provided by physicians was that payments were “perceived” as unrelated to the presentation or article in question. But in fact, a median of 45% of the non-disclosed payments from pharmaceutical companies or device manufacturers were directly or indirectly involved in the published or presented academic work. We also found that smaller monetary amounts and payment relevance (to the article or presentation) are the most commonly reported predictors of nondisclosure amongst a variety of payment, author, article, and journal-related factors.

Strengths and weaknesses of the study

Strengths of our review include the robust search strategy, which involved a systematic search of three databases using a broad search strategy. We identified a large number of studies enabling us to characterize discrepancies in self-reported payments across multiple settings and disciplines. We were also able to stratify discrepancies across articles, authors, disclosure statements, and payments in order to provide estimates of discrepant reporting at each of these levels.

The limitations of our studies are largely due to the limitations of the existing research base. Our meta-analysis combines data across studies in order to estimate the rate of discrepant reporting with more precision than is possible from a single study alone. The primary limitation of this, as

with any overview, is that the physician population and methodologies used for assessment of COI are not the same across studies. There are also limitations because many “objective data sources” relied in most cases on disclosures by industry, which is potentially problematic. Inconsistencies in these databases, which could represent under or over-reporting by industry, have been reported.[26] While physicians are able to review this data, a challenging payment dispute process may inhibit them from attempting to correct inaccuracies.[56] Nonetheless, given that many countries have made industry disclosures mandatory and regulated, we believe this is the most comprehensive source of all payment data for our analysis. Finally, with the exception of two studies from Denmark, our study is limited to those from physicians in the United States. Hence it does not include payments from foreign sponsors or payments to foreign physicians, which may not be generalizable to other countries.

Strengths and weaknesses in relation to other studies

Our results verify and extend those reported by Wayant et al [57] who identified ten studies that examined, exclusively amongst authors of clinical practice guidelines, the truthfulness of the reporting by physicians of financial relationships with industry. Those authors identified a pooled accuracy of 18% between actual and reported financial COIs. Our review extends these findings by evaluating physician disclosure practices among authors of both CPGs and other publications, presenters of abstracts and papers at scientific meetings, and individuals organizing academic meetings. We further characterized discrepancies by examining putative factors that might be associated with nondisclosure.

Meaning of the study: possible explanations and implications for clinicians and policymakers

Putative explanations for the high rates of nondisclosure of financial COIs by physicians rely upon claims that guidelines specifying what is relevant to report are subjective and open to interpretation, although most guidelines are standardized to reduce variation and leave little room for authors to decide what relationships may be relevant to report. In 2009, a detailed disclosure form was introduced by the ICMJE, requiring all authors to disclose all relevant COI within the past 36 months, encouraging physicians to err on the side of over disclosure.[60] Our review found that the accuracy of disclosure was not associated with that journal’s disclosure requirements or its endorsement of ICMJE policy requirements[46], which may be related to variability of enforcement. Despite efforts to standardize the disclosure process, physicians many continue to omit reporting relevant disclosures due to false convictions that their relationships with industry do not apply to their work.[12] Our analysis found, however, that a significant proportion of discrepancies were related to the academic work in question, suggesting that physicians may not be the most accurate assessors of payment relevance.

The ICMJE form requires authors to specify all relationships with industry, regardless of the amount of compensation. While the amounts of unreported payments varied across studies, we found that smaller amounts were more likely to be unreported compared to larger payment amounts. In addition, general payments such as food and beverage, travel and lodging were most likely to go unreported. This is arguably due to a common perception that small expenses or travel costs are unlikely to affect decision-making or behavior. However, the often-advanced idea that small payments from industry are unlikely to affect physician judgment in research or medical

practice is not supported by the literature. By contrast it is clear that feelings of obligation and impulses toward reciprocity are not related to the size of a gift;[61, 62] small as well as larger gifts are associated with increased rates of prescribing brand-name medications.[63]

The findings of this systematic review and meta-analysis suggest that changes to COI disclosure policies are required in the interests of transparency, otherwise self-reported disclosure will continue to remain an empty panacea. One possible solution is for journals to provide authors with prepopulated disclosure forms with data extrapolated from public databases. Authors should be provided an opportunity to verify each COI, and provide justification for payments they consider inaccurate or irrelevant. Ultimately, full transparency depends on moving away from entirely self-reported disclosures of payments from industry by physicians, and will require well-enforced policies—the violation of which result in tangible consequences. Physicians who are found to not disclose their relationships with industry should expect to face misconduct charges and sanctions.[64] While verifying each author's disclosures may require significant time and effort by journal editors, the falsification of information that others rely on to assess that work should be an academic offence that is not tolerated.

Unanswered questions and future research

Currently, ICJME policies require authors to only report COI within the past 36 months. However, further research is warranted to ascertain the length of time during which physicians are susceptible to industry influence after receiving funds.

Conclusions

Physicians self-report of financial COI are highly discrepant with objective data sources reporting payments from industry. Stronger policies are required by journal editors to reduce reliance on physician self-reporting of financial COI.

Declarations

Transparency declaration: We affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination declaration: We have reported whether we plan to disseminate the results to study participants and or patient organisations OR stated that dissemination to these groups is not possible/applicable.

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Consent for publication: Not applicable

Availability of data and materials: No additional data available.

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Patient and Public Involvement: It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

Authors contributions: CT developed the research question, performed the literature search, assisted with developing the search strategy, extracted the data and assessed risk of bias, and was a major contributor in writing the paper. AK developed the search strategy, completed screening and assessed risk of bias, and was a contributor in writing the paper. XL completed screening, extracted the data and assessed risk of bias, and was a contributor in writing the paper. AL completed all statistical analysis and was a contributor in writing the paper. ST assisted with the qualitative analysis and was a contributor in writing the paper. NO is the senior author and provided guidance throughout the process. All authors read and approved the final protocol.

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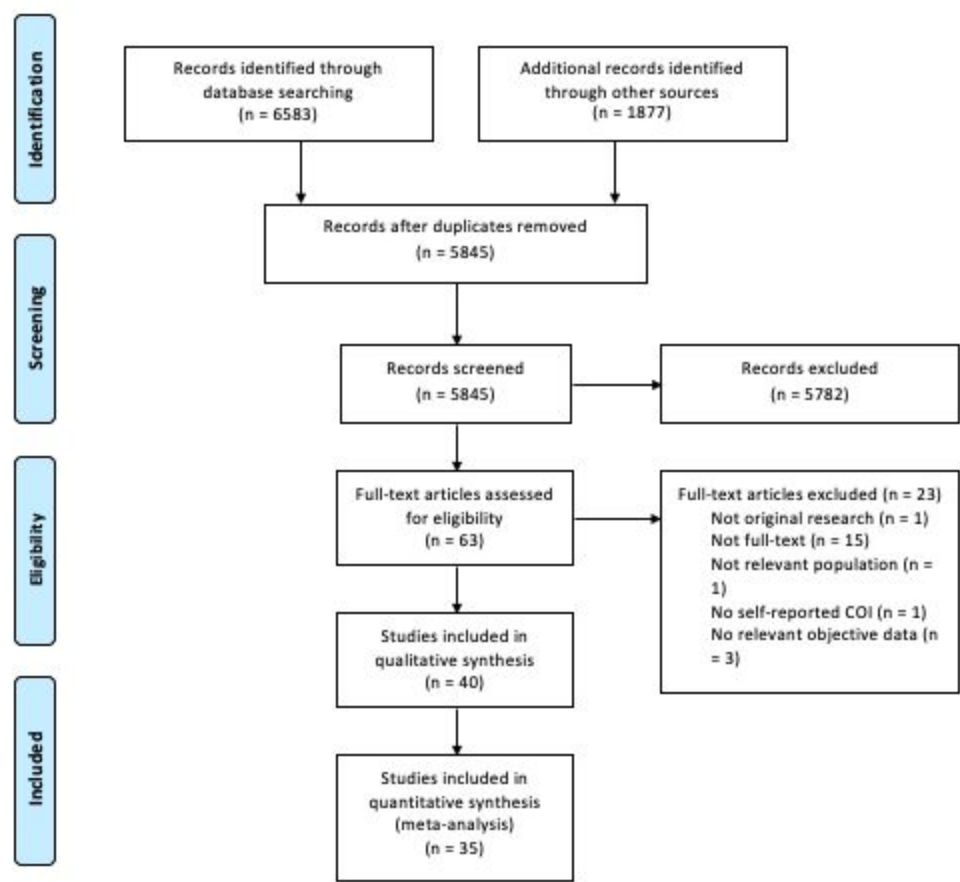


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analysis flow diagram.

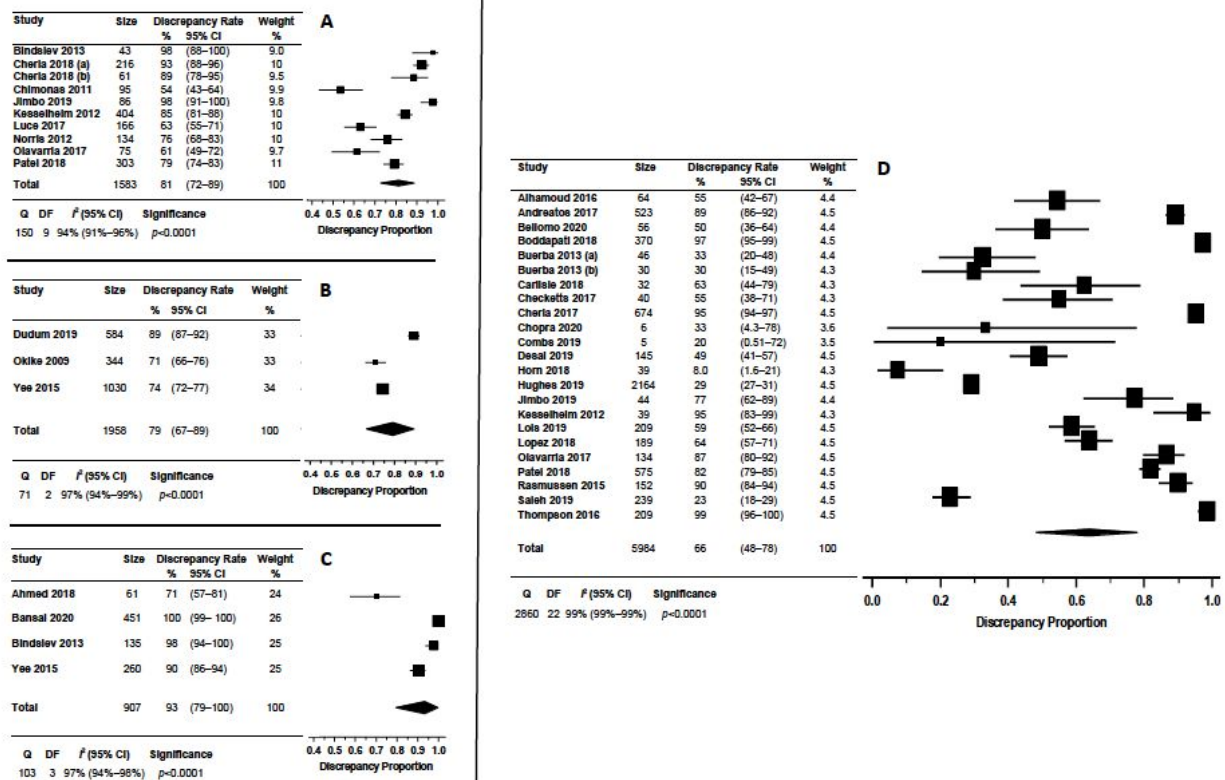


Figure 2. Forest plot illustrating the number conflicts of interest (COI) discrepancies, defined as the number of unreported COI as a proportion of the total number of conflicts of interest. Panel A represents the COI discrepancies at the article level. Panel B represents the COI discrepancies at the payment level. Panel C represents the COI discrepancies at the disclosure level. Panel D represents the COI discrepancies at the author level.

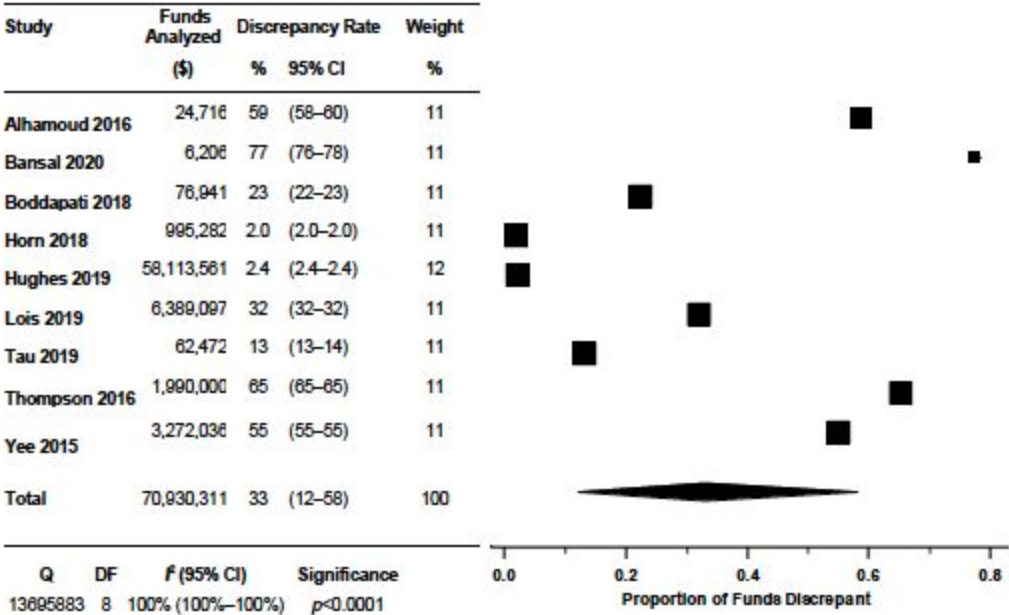


Figure 3. Forest plot illustrating the reported funding discrepancies, defined as the amount of funding unreported as a proportion of the total funds received.

Supplementary 1. Search strategy for Medline.

#	Searches
1	exp "conflict of interest"/
2	((conflict* or compet* or financial) adj1 (interest* or disclos*)).tw,kf.
3	exp Financial Support/es [Ethics]
4	(allergist* or anesthesiologist* or anesthetist* or cardiologist* or clinician* or dermatologist* or diabetologist* or doctor* or endocrinologist* or gastroenterologist* or general practitioner* or geriatrician* or gynecologist* or haematologist* or hospitalist* or internist* or medical resident* or neonatologist* or nephrologist* or neurologist* or neurosurgeon* or obstetrician* or oncologist* or ophthalmologist* or otolaryngologist* or pathologist* or pediatrician* or physician* or podiatrist* or psychiatrist* or pulmonologist* or radiographer or radiologist* or rheumatologist* or surgeon* or urologist*).tw,kf.
5	1 or 2 or 3
6	4 and 5



PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	3
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	—
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	5



PRISMA 2009 Checklist

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	16
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	7 onwards
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	7 onwards
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	19
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	19
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	21
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	22

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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Discrepancies in Self-Reported Financial Conflicts-of-Interest Disclosures by Physicians: Systematic Review and Meta-Analysis

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Discrepancies in Self-Reported Financial Conflicts-of-Interest Disclosures by Physicians: Systematic Review and Meta-Analysis

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Abstract

Background: There is a high prevalence of financial conflicts-of-interest (COI) between physicians and industry.

Objectives: To conduct a systematic review with meta-analysis examining the completeness of self-reported financial COI disclosures by physicians, and identify factors associated with non-disclosure.

Data sources: Medline, Embase, and PsycInfo were searched for eligible studies up to April 2020 and supplemented with material identified in the references and citing articles.

Data extraction and synthesis: Data were independently abstracted by two authors. Data synthesis was performed via systematic review and exploratory random-effects meta-analyses of eligible studies.

Main outcomes and measures: The proportion of discrepancies between physician self-reported disclosures and objective payment data was the main outcome. The proportion of discrepant funds and factors associated with non-disclosure were also examined.

Results: 40 studies were included. Most undisclosed COI were those related to food and beverage, or travel and lodging. While the most common explanation for failure to disclose was perceived irrelevance, a median of 45% of non-disclosed payments were directly or indirectly related to the work. A smaller monetary amount was the most commonly reported factor associated with nondisclosure. The exploratory meta-analyses demonstrated high heterogeneity between studies across all five meta-analyses ($I^2=94-99\%$). The pooled proportion of COI discrepancies at the article level was 81% (range: 54–98%; 95% Confidence Interval (CI): 72%–89%), 79% at the payment level (range: 71–89%; 95% CI: 67–89), 93% at the authorship level (range: 71–100%; 95% CI: 79–100%), and 66% at the author level (range: 8–99%; 95% CI: 48%–78%). The proportion of funds discrepant was 33% (range: 2–77%; 95% CI: 12–58%).

Conclusions: Physician self-reports of financial COI are highly discrepant with objective data sources reporting payments from industry. Stronger policies are required to reduce reliance on physician self-reporting of financial COI and address non-compliance.

Strengths and limitations of this study

- The study characterized discrepancies in self-reported payments across multiple settings and disciplines.
- The results were stratified across different levels in order to provide more accurate estimates of discrepant reporting.
- The population and methodologies used for assessment of conflicts of interest are not the same across studies.
- Many of the objective data sources used in this study relied on disclosures by industry, which may have inconsistencies.
- The study is largely limited to physicians in the United States and may not be generalizable to other countries.

Background

Financial conflicts-of-interest (COI) between physicians and industry commonly occur, and are a longstanding area of public concern.[1, 2] They occur in situations where a person has a moral obligation to exercise judgment in another’s service and, at the same time, an interest tending to interfere with the proper exercise of judgment in that relationship. Under this definition “Judgment” refers to intelligent activity requiring more than mechanical rule following; “interest” refers to personal financial benefit, family interest or any special influence or loyalty which could undermine the performance of one’s duty to exercise one’s judgment objectively.”[3] Financial COI have the potential to undermine the integrity of medical research, education, and practice.[3, 4, 5] Considerable evidence indicates that financial COI may influence the conduct and reporting of research, increase the likelihood of research outcomes favoring the sponsor (usually the pharmaceutical or device industry).[1, 6] Additionally, financial COI may be associated with inappropriate prescribing patterns.[7]

Financial COI occur in situations in which there is transfer of payment from industry to physicians. This is independent of whether these payments are disclosed. The National Academy of Medicine, a US non-profit organization which is independent of government and provides policy recommendations for public health and science, asserts that accurate disclosures of conflicts of interest protect the integrity of professional judgment and preserve the public trust in physicians.[5] Over the past decade, many academic institutions and medical journals have adopted guidelines which guide disclosures of financial COI in a putative effort to increase transparency, encourage critical appraisal of research findings, and enable research into the effects of COI.[8] Unfortunately, disclosure has not been shown to eliminate bias.

While there has emerged credible criticism that disclosure is not a solution to the management of COI,[9, 10] financial COI disclosures have become a quintessential part of conducting and publishing research, delivering academic presentations and educating medical students at this time. Complicating the issue is that disclosure of financial COIs relies almost entirely on self-reporting by those benefiting from financial gain. There has traditionally been no means of verification of the correlation between payments received, and disclosure. Indeed many physicians have been reported to omit, or incompletely disclose relevant COI, even in situations in which guidelines require this disclosure,[2, 11-14] resulting in incorrect information provided to those reading, interpreting, or using the data reported. The extent of and factors associated with this under-reporting of financial COI by physicians may be less well studied than warranted by this important issue. To date, there has not been a systematic search of the literature identifying studies comparing actual and disclosed financial COI. Our study aims to systematically examine the literature on completeness of self-reported financial COI disclosures by physicians, and identify the factors associated with non-disclosure.

Methods

This systematic review was conducted according to the standards and guidelines established by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) and the fourth edition of the Joanna Briggs Institute Reviewer's Manual.[15, 16] Methods of the analysis and inclusion criteria were specified in advance and documented. Our protocol is publicly available (<https://osf.io/fzhd7>).

Eligibility Criteria

We included studies that sought to examine discrepancies between financial COI which were reported by physicians, and the objective data which documented payments from industry to the physicians as either the primary or secondary objective. We considered a discrepancy to be present if data provided information about relevant financial support that was not reported by the physicians themselves.. We considered objective payment data to be any data that was not reported by physicians themselves. Comparisons between self-reported disclosures were not eligible for our study as these were not considered to be complete. We examined only original, peer-reviewed literature in the English language including cross-sectional analyses, prospective cohorts, and retrospective cohorts. Published conference posters and abstracts were not eligible for inclusion as we required full-text manuscripts to optimize the completeness of our data. Articles were excluded if they did not focus on physicians, did not assess COI involving payments from the pharmaceutical (or device manufacturing) industry, or if they did not have available an objective comparator. We reviewed studies that focused on disclosures in any setting, such as research publications, clinical practice guidelines, academic presentations, or conference committees.

Information Sources

We consulted a University of Toronto research librarian to help develop the search strategy. We searched Ovid MEDLINE (1946 – April 2020), Ovid EMBASE (1947 – April 2020), and PsycInfo (1806 – April 2020) using a combination of both MESH subject headings (exploded) and key words. Subject-specific search terms adapted from previously published systematic reviews on financial COI (“conflict of interest”, “financial support”, and “funding”) were combined with a filter to retrieve studies related to physicians.[6, 17, 18] The search strategy is included in Appendix 1. In addition, we reviewed the references of included papers and searched for studies that have cited these papers using SCOPUS.

Study Selection

Study selection was completed in duplicate by two independent, parallel reviewers (AK, XL) using title, abstract and full-text screening. Disagreements between reviewers were resolved

independently by a blinded third reviewer (CT). Covidence was used for both data management and screening.

Data Collection

To further refine extraction categories we developed, *a priori*, a data extraction sheet, and pilot-tested it on ten randomly selected studies we had included. Data were extracted in duplicate by two independent, parallel reviewers (CT, XL). Disagreements were resolved by discussion between the two reviewers and subsequent consultation with a third author (AK).

From each study, we extracted the clinical focus, study design, primary objective, sources of data collection, time of payments, how COI were defined, number and monetary amount of total COI, number and monetary amount of undisclosed COI, number of relevant undisclosed COI, types of undisclosed COI, factors associated with undisclosed COI, reasons for non-disclosure, and association of nondisclosure with study outcomes.

We assessed the risk of bias of each included study using a modified version of the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Studies Reporting Prevalence data. The JBI checklist is used to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. Individual studies are scored as either “Yes,” “No,” or “Unclear” for each checklist item. We considered a sample greater than 1000 to be adequate in the absence of an appropriate sample size calculation. The risk of bias assessment was done in duplicate by two independent, parallel reviewers (AK, XL). Disagreements were resolved by discussion between the two reviewers and subsequent consultation with a third author (CT).

Data Synthesis

The included studies were described and summarized by qualitative synthesis. We also conducted a meta-analysis of the studies which reported the data necessary to compute the proportion of payments discrepant and the amount of funds discrepant.

Statistical Analyses and Outcomes

Our primary outcome was the proportion of COI which was discrepant: that is, the proportion in which objective documentation of funding had not been self-reported. Our secondary outcome was the proportion of funds discrepant: that is the amount of funds (US dollars) which had not been self-reported. Disclosures that were reported by physicians, but not reported by the objective data source, were not considered to be discrepancies in this study.

Data were stratified into four groups according to whether they described discrepancies among authorships, authors, articles, or payments. Refer to table 1 below to better understand how we use these terms. In each case, the proportion of COI identified as discrepant between self-reporting and objective was defined as the number undisclosed COI over the total number of COI.

Table 1. Definitions of groups used to stratify data.

Group	Definition	Example
Authorship	One instance of disclosure by one individual. One authorship may involve multiple transactions.	Sorting by authorship can involve identifying any discrepancies in COI reporting by one author in a single published work.
Author	A unique individual who can have more than one authorship. An author may be involved in multiple authorships.	Sorting by author can involve identifying any discrepancies in COI reporting by one author among a number of publications.
Article	A group of individuals with authorships for a single published work	Sorting by article involves identifying any discrepancies in COI reporting by any author of a single published work.
Payment	A single transaction between industry and authors.	Sorting by payment involves identifying any discrepancies in COI reporting by one individual for a single transaction.

Each payment was treated as equal regardless of the amount of funding or the amount discrepant. The proportion of funds that was identified as discrepant between self-reporting and objective data was defined as the amount of funding not disclosed as a proportion of the funds recorded in the payment database. The proportion of COI identified as discrepant between self-reporting and objective data and the proportion of funds identified as discrepant between self-reporting and objective data were pooled in an exploratory meta-analysis and analyzed using a random-effects model. Exploratory analyses were performed to determine the degree of heterogeneity between studies and to quantitatively determine the proportion of COI and funds discrepant across studies. A random-effects model was used because of the expected methodological heterogeneity between studies. The I^2 statistic was used to measure heterogeneity between studies and $p < 0.05$ was considered statistically significant. Statistical analysis was performed using MedCalc Statistical Software v19.2.6.[19]

Results

Search Results

Figure 1 illustrates the PRISMA flow diagram. Searches and other data sources provided a total of 8460 citations. After removing duplicates, 5845 studies remained. Of these, we discarded 5781 studies after reviewing the abstracts which indicated the papers did not meet the inclusion criteria. One additional study was discarded because the full text of the study was not available. We assessed the full text of the remaining 63 citations. We identified a total of 40 studies for inclusion in the systematic review, 12 of which were identified by searching reference lists and citing articles. Inter-rater reliability for study screening for titles/abstract and full-text screening was 99.5% and 91.2% respectively. The authors were in substantial agreement or better with a calculated Kappa of 0.77 and 0.81 respectively.

Characteristics of Included Studies

Table 2 summarizes the characteristics of the 40 studies included in this analysis. All studies had a cross-sectional design. Thirty-eight studies were conducted in the United States and two in Denmark.[20, 21] Six studies assessed disclosures from academic meetings[11, 13, 22, 23, 24, 25], ten assessed disclosures in clinical practice guidelines[21, 26, 27, 28, 29, 30, 31, 32, 33, 34], 22 assessed those in other publications[12, 14, 20, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54], and one assessed those in both an academic meeting and publications.[51] All studies examined self-reported disclosures by physician authors or presenters of academic work; three studies also reported disclosures by conference organizers.[11, 23, 24] Most studies examined disclosures of physicians conducting work within a common discipline; four examined disclosures of physicians across a variety of disciplines.[12, 20, 37, 39] Disclosures in surgical disciplines were most commonly investigated; eight studies focused on disclosures of physicians working in orthopedic surgery[11, 13, 38, 40, 43, 46, 47, 54], three of those working in plastic surgery[14, 42, 51], two of those working in otolaryngology[23, 29], two of those working in urology[32, 53], and three of those working in other surgical specialties.[24, 45, 48] Aside from one which used data from the United States Department of Justice investigations,[37] all studies used industry-reported payment data as the objective comparison; of these 39 studies reliant upon industry-reported payment data, 30 examined data from the Centers for Medicare and Medicaid Services' Open Payments Database (OPD)[12, 14, 23, 24, 25, 27, 28, 29, 30, 31, 32, 33, 34, 35, 38, 39, 40, 41, 42, 43, 44, 45, 47, 48, 49, 50, 51, 53, 54, 55], two studies used the ProPublica's Dollars for Docs database[26, 36], two studies used both of these sources[23, 52], two studies used the Danish Health and Medicines Authority's public disclosure list[20, 21], and three studies referenced the web pages of device manufacturers.[11, 13, 46] All included studies examined different data sets except two [11, 46] both of which examined the same data set involving five manufacturers of total hip and knee prosthesis in 2007. Most studies examined COI involving

relatively recent financial relationships; one study[37] examined relationships dating back to 1999. Two studies[49, 50] did not specify the time period studied.

Proportion of COI discrepant

As outlined above the included studies examined COI involving articles, authors, authorships, or payments. The majority of studies defined discrepancies as one or more undisclosed COI, but three studies considered a discrepancy to occur only when all COI were inaccurately disclosed by an author.[36, 47, 54]

An exploratory meta-analysis was performed to summarize the studies that examined the accuracy of self-reported financial COI at the article, payment, disclosure, and author level. Heterogeneity of pool data was high across all four levels examined with $I^2=94-99\%$. For completeness, we have reported the results of the meta-analysis in Appendix 2. The pooled proportion of the 10 studies (1583 total articles pooled) reporting discrepancies at the article level was 81% (range: 54–98%; 95% Confidence Interval (CI): 72%–89%) (Appendix 2, Panel A). The pooled proportion of the three studies (1958 total payments pooled) reporting discrepancies at the payment level was 79% (range: 71–89%; 95% CI: 67–89) (Appendix 2, Panel B). The pooled proportion of the four studies (907 total disclosures pooled) reporting discrepancy at the authorship level was 93% (range: 71–100%; 95% CI: 79–100%) (Appendix 2, Panel C). The pooled proportion of the 23 studies (5984 total authors pooled) reporting discrepancy at the author level was 66% (range: 8–99%; 95% CI: 48%–78%) (Appendix 2, Panel D).

Table 2. Characteristics of included studies.

Author Year; Country	Study Design	Focus of Research	Self-Disclosure Source	Objective Data Source	Level of Data	Time of Payments
Ahmed 2018[22]; United States	Cross-sectional	Radiation-oncology	Authors of presentations at academic meeting	OPD	Authorship	2013-2015
Alhamoud 2016[26]; United States	Cross-sectional	Cardiology	Authors of CPGs	DFD	Author	2009-2012

Andreatos 2017[33]; United States	Cross-sectional	Various disciplines	Authors of CPGs	OPD	Author	2013-2014
Bansal 2020[34]; United States	Cross-sectional	Gastroenterology	Authors of CPGs	OPD	Authorship	2013-2017
Bellomo 2020[36]; United States	Cross-sectional	Vascular	Authors of publications	DFD	Author	2013-2016
Bindslev 2013[21]; Denmark	Cross-sectional	Various disciplines	Authors of CPGs	Danish Health and Medicines Authority disclosure list	Article, Authorship	2007-2012
Boddapati 2018[35]; United States	Cross-sectional	Sports medicine	Authors of publications	OPD	Author	2014-2015
Boyll 2019[51]; United States	Cross-sectional	Plastic surgery	Authors of publications	OPD	Article, Author, Authorship	2013-2016
Buerba 2013[13]; United States	Cross-sectional	Spine surgery	Authors of presentations at academic meeting	Company web pages	Author	2010

Carlisle 2018[32]; United States	Cross-sectional	Urology	Authors of CPGs	OPD	Author	2012-2014
Checketts 2017[31]; United States	Cross-sectional	Dermatology	Authors of CPGs	OPD	Author	2013-2015
Cherla 2017[49]; United States	Cross-sectional	Pulmonology, hematology, orthopedics, cardiac surgery, otorhinolaryngology	Authors of publications	OPD	Article, Author	NR
Cherla 2018a[48]; United States	Cross-sectional	Surgery	Authors of publications	OPD	Article	2012-2016
Cherla 2018b[50]; United States	Cross-sectional	Ventral hernia	Authors of publications	OPD	Article	NR
Chimonas 2011[46]; United States	Cross-sectional	Orthopedics	Authors of publications	Company web pages	Article, Author	2017
Chopra 2020[52]; United States	Cross-sectional	Various disciplines	Authors of publications	OPD and DFD	Author	2013-2015
Combs 2019[30]; United States	Cross-sectional	Various disciplines	Authors of CPGs	OPD	Author, Payment	2014-2017

Desai 2019[23]; United States	Cross- sectional	ENT	Authors of presentatio ns at academic meeting	OPD and DFD	Author	2013-2015
Dudum 2019[27]; United States	Cross- sectional	Cardiology	Authors of CPGs	OPD	Author, Payment	2013-2017
Fu 2018[38]; United States	Cross- sectional	Orthopedic surgery	Authors of publication s	OPD	Authorshi p	2014-2015
Garrett- Mayer 2020[55]; United States	Cross- sectional	Oncology	Authors of presentatio ns at academic meeting and publication s	OPD	Author	2016-2017
Horn 2018[29]; United States	Cross- sectional	Otolaryngolog y	Authors of CPGs	OPD	Author	2013-2016
Hughes 2019[54]; United States	Cross- sectional	Orthopedic surgery/sports medicine	Authors of presentatio ns at academic meeting	OPD	Author	2015
Janney 2019[47]; United States	Cross- sectional	Orthopedic surgery	Authors of publication s	OPD	Authorshi p	2013-2016

Jimbo 2019[53]; United States	Cross-sectional	Urology	Authors of publications	OPD	Article, Author	2013-2016
Kesselheim 2012[37]; United States	Cross-sectional	Various disciplines	Authors of publications	United States Department of Justice investigations	Article, Author	1999-2007
Lois 2019[25]; United States	Cross-sectional	Gastroenterology	Authors of presentations at academic meeting	OPD	Author	2017
Lopez 2018[14]; United States	Cross-sectional	Plastic surgery	Authors of publications	OPD	Author	2013
Luce 2017[42]; United States	Cross-sectional	Plastic surgery	Authors of publications	OPD	Article	2015
Norris 2012[12]; United States	Cross-sectional	Various disciplines	Authors of publications	DFD	Article	2009-2010
Okike 2009[11]; United States	Cross-sectional	Orthopedic surgery	Authors of presentations at academic meeting	Company web pages	Payment	2007

Olavarria 2017[41]; United States	Cross- sectional	Ventral hernias	Authors of publication s	OPD	Article, Author	2012-2014
Patel 2018[45]; United States	Cross- sectional	Robotic surgery	Authors of publication s	OPD	Article, Author	2013-2014
Rasmusse n 2015[20]; Denmark	Cross- sectional	Various disciplines	Authors of publication s	Danish Health and Medicines Authority's public disclosure list	Author	2010-2013
Ross 2020[40]; United States	Cross- sectional	Hand surgery	Authors of publication s	OPD	Author, Authorshi p	2014-2016
Saleh 2019[28]; United States	Cross- sectional	Oncology	Authors of CPGs	OPD	Author	2013-2017
Somerson 2020[43]; United States	Cross- sectional	Orthopedic surgery	Authors of publication s	OPD	Authorshi p	2015-2016
Tau 2019[39]; United States	Cross- sectional	Various disciplines	Authors of publication s	OPD	Author	2013-2015
Thompso n 2016[24];	Cross- sectional	Obstetrics/Gy necology	Authors of presentatio ns at	OPD	Author	2014

United States			academic meeting			
Yee 2015[44]; United States	Cross-sectional	Ophthalmology	Authors of publications	OPD	Authorship, Payment	2013

Abbreviations: CPG: Clinical Practice Guideline; OPD: Dollars For Docs (ProPublica); Open Payments Database (Centers for Medicare and Medicaid Services)

Relevance of discrepant COI

Nine studies reported the proportion of relevant discrepancies.[8, 11, 14, 20, 24, 34, 40, 42, 48] Discrepancies were reported as being considered relevant if the payments provided were directly, or indirectly, related to the topic of the presentation, clinical practice guidelines, or another publication. Because only nine studies reported these data, and each had examined discrepancies at a different level, we elected to not pool this outcome. The proportion of relevant discrepancies ranges from 6% to 99%. The median proportion of relevant discrepancies is 45%. There is considerable heterogeneity across studies.

Proportion of funds (of the total funds reported) that were discrepantly reported

Nine studies reported the proportion of total amounts which were discrepantly reported. However, similar to the proportion of COI discrepant, there was high heterogeneity between studies (I²=100%). The exploratory analysis that pools the proportion of nine studies (\$70,930,311 total funds pooled) reporting funding discrepancies are reported in Appendix 3. The pooled proportion of total amounts which were discrepant was 33% (range: 2–77%; 95% CI:12–58%).

Types of COI that were discrepantly reported

Specific types of financial COI were reported as undisclosed in nine studies. These were similar across studies.[22, 27, 28, 31, 34 35, 38, 43, 55] The most common category of undisclosed COI was general payments. According to the payment databases, general payments include food and beverage, travel and lodging, consulting, royalties and licenses, non-consulting services (including serving as faculty or speaker at an event other than continuing education), payments for education, speaker and faculty fees, and honoraria.[27, 34, 35, 38, 43, 55] Within this category, food and beverage were identified by three studies as among the most frequently undisclosed.[38, 43, 55] Two studies identified travel and lodging[38, 55], two identified consulting and speaking[22, 27],

and one identified non-consulting services (including serving as faculty or speaker at an event other than continuing education) as the most commonly undisclosed.[27] Two studies identified research payments as the most commonly undisclosed[22, 28], and another two studies identified them as commonly undisclosed.[34, 35]

Factors associated with discrepant reporting

A total of 15 out of 40 studies reported factors that are associated with discrepant reporting.[11, 13, 14, 22, 26, 33, 34, 35, 37, 40, 45, 46, 47, 49, 51] We conducted a narrative summary of these factors. Table 3 summarizes the results of each study reporting factors that were associated with discrepant reporting of financial COIs. We organized factors into four themes: factors related to author characteristics (e.g., academic affiliation), payment characteristics (e.g., amount of the payment from industry), article characteristics (e.g., level/hierarchy of evidence, such as systematic review versus commentary), and journal characteristics (e.g., impact factor). Of these, author and payment were the most commonly reported factors that were associated with discrepant reporting.

Three studies examined the influence of an author’s gender in discrepant reporting.[22, 34, 35] There were no consistent result regarding the outcomes. Six studies examined whether the position of an author on a scientific article influenced discrepant reporting.[34, 35, 37, 40, 46, 51] The data concerning author position was conflicting. Some studies found that prominent (first, last, or sole) authors were associated with discrepant reporting, while other studies found that other (middle) authors were associated with discrepant reporting. Two studies reported no association across authorship positions.[34, 37]

Other author-related factors include an affiliation with an academic institution, the physician specialty, and physician role at an academic meeting (e.g., organizer vs attendee). Two studies identified the influence of author affiliations on undisclosed payments;[14, 34] both reported that authors with academic affiliation were significantly more likely to have undisclosed payments compared than those without. One study reported that physician’s roles are associated with reporting behavior.[11] At one academic meeting, physicians who did not serve as board members or committee members, or who were not symposium presenters or instructional-course lecturers at the annual meeting were less likely to disclose. Four studies reported the associations between physician specialty and discrepant reporting.[33, 37, 45, 49] Three of these studies found an association[33, 45, 49]; one found no difference among specialties[37]. Patel (2018) reported that general surgeons were more likely to have discrepant reporting than those in other surgical specialties.[45] Cherla (2017) found that manuscripts related to hematology exhibited the highest discrepant reporting, while manuscripts related to otolaryngology were associated with the lowest rates.[49] Andreatos (2017) reported that authors of guidelines in general

medicine, orthopedics, trauma, pulmonology, gastroenterology, and radiology had significantly higher rates of discrepant reporting than did authors of guidelines in other specialties.[33]

Six studies reported on the association of the value of payments that were not disclosed.[11, 13, 14, 26, 33, 35] Five found that authors who received smaller total payments or individual payments of lesser value were associated with discrepant reporting [11, 13, 14, 26, 35] Studies differed in what was reported to be considered “significant” amounts, from \$500[14], \$10,000[11, 26], \$100,000[11, 13], to \$500,000.[35] The sixth study was the only one to report no statistically significant association between discrepant reporting and the value of the payments involved.[33]

Five studies commented on other payment-related factors.[11, 14, 33, 35, 46] One study found that payments made to a group or organization were more likely to be undisclosed when compared to payments made to an individual physician.[11] Additionally, when payments did not include an in-kind component they were less likely to be reported.[11] Payments that were unrelated to the topic of the presentation or article were more likely to be undisclosed than directly or indirectly related payments.[11, 14, 46] However, not all payment types were equally likely to be unreported. “General payments” (such as food and beverage, travel and lodging) were more likely to be incompletely or inaccurately reported than “research payments”.[33]

Three studies commented on article-level factors associated with discrepancies.[35, 37, 45] One study found that when stratified by the level of evidence, authors of papers of higher levels of evidence (level of evidence ≥ 1) were significantly more likely to have discrepancies than those authors of papers of lower levels of evidence.[35, 37] Another study found that there was no difference between comparative (observational studies, randomized controlled studies or meta-analyses/systematic reviews) and non-comparative studies (case series, technique description or editorials/comments).[45] Additionally, article citation index per year since publication was not associated with adequacy of disclosure.[37]

Three studies described the association of journal characteristics with discrepant reporting.[37, 45, 46] Two studies found no statistically significant association with journal impact factor.[37, 45] Moreover, one study found that the accuracy of disclosures did not vary with the strength of journals’ disclosure policies, and there was no association between a journal’s endorsement of specific International Committee of Medical Journal Editors (ICMJE) policy recommendations, and discrepant reporting.[46]

Table 3. Results of studies investigating factors associated with discrepant reporting.

Study	Factors Evaluated	Significant Results
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Ahmed 2018[22]	At least one disclosure* Duration of presentation Sex* Word count Year of presentation Words per second (spoken during presentation)*	On univariable analysis, having at least one disclosure (OR, 2.62; 95% CI, 1.02-5.24) and male sex (OR, 3.76; 95% CI, 1.45-12.8) were associated with having a discrepancy. On multivariable regression, only the number of words per second was correlated to having a discrepancy (OR, 1.08; 95% CI, 1.01-1.80).
Alhamoud 2016[26]	Payment amount*	Payments ≥\$10,000 were 2.8 times more likely to be reported than modest or no payments (P=0.001).
Andreatos 2017[33]	Specialty* Type of payment* Total payment value	Authors of general medicine (P=0.02), orthopedics/ trauma (P=0.01), pulmonology (P=0.02), gastroenterology (P=0.02), and radiology (P=0.03) guidelines had significantly less accurate COI disclosures compared to other specialties. Authors were significantly less likely to inaccurately report “research payments” compared to “general payments” (75.5% vs 87.3%; P=0.02).
Bansal 2020[34]	Sex* Academic affiliation* Authorship order	Male authors (odds ratio, 2.23; 95% confidence interval, 1.47-3.39) and academically affiliated authors (odds ratio, 8.87; 95% confidence interval, 5.57-14.13) were significantly more likely to have undeclared payments (P<0.001).

Boddapati 2018[35]	Payment amount* Authorship order* Sex* Level of evidence* Type of payment*	Authors with total payments >\$500,000 were less likely to be discrepant than those earning <\$10,000 (16.1% vs 85.3%; $P<0.001$). First authors had a lower percentage of payment values with discrepancy versus middle authors (13.8% vs 31.9%; $P=0.001$). Men had a lower percentage of payment values with discrepancy as compared with women (22.3% vs 95.3%; $P<0.001$). The discrepancy rate was lowest in the level of evidence 1 subgroup as compared with the other groups, such as level of evidence 2 (75.0% vs 90.3%; $P=0.013$). Authors were least discrepant in general payments compared to research and ownership payments (17.2% vs 32.7% vs 47.5%; $P<0.001$).
Boyll 2019[51]	Authorship order*	A middle author is less likely to have discrepancies than the first or last author (OR, 3.593; 95% CI, 1.211-10.657; $P=0.0212$).
Buerba 2013[13]	Payment amount*	Those who received payments <\$100,000 from Medtronic were more likely to have discrepancies in their disclosures than those who received payments >\$100,000 ($P=0.009$).
Cherla 2017[49]	Specialty*	Between the medical and surgical published literature, the discordance rate for manuscripts differed significantly (71.5% vs 60.7%; $P=0.01$). Hematology manuscripts exhibited the highest incomplete disclosure rate while Otorhinolaryngology manuscripts showed the lowest (75.0% vs 42.0%; $P<0.001$).
Chimonas 2011[46]	Authorship order* Payment relatedness* Journal policy	First, sole, or senior authors were more likely to disclose than middle authors (54% vs 32%; $P=0.03$). Articles related to company payments were more likely to disclose compared to unrelated payments (50% vs 11%; $P=0.04$).

Janney 2019[47]	Year of publication	N/A
Kesselheim 2012[37]	Type of article* Specialty Authorship order Journal impact factor Article citation index	The researchers found that commentaries were significantly less likely to have adequate disclosure compared to articles reporting studies or trials (OR 0.10; 95% CI 0.02-0.67; P=0.02).
Lopez 2018[14]	Academic affiliation* Payment relatedness* Payment amount*	Nonacademic authors were 6.25 times more likely to disclose COI compared with authors with an academic affiliation (P<0.0001). Authors who received \$500 or more in transactions of value were 9.09 times more likely to disclose COI compared with authors who received less than \$200 (P<0.0001). Authors whose COI was related to the topic of their article were 2.75 times more likely to disclose conflicts of interest compared with authors whose COI was unrelated to the topic of their article (P<0.0001).
Okike 2009[11]	Payment amount* Payment made to an individual physician* Payment with in-kind component* Physician role* Payment relatedness*	Payments were more likely to have been disclosed if they exceeded \$10,000 than if they did not (64.4% vs 42.9%; P<0.001), were directed toward an individual physician rather than a company or organization (78.1% vs 45.9%; P=0.04), or included an in-kind component (79.0% vs 46.3%; P=0.002). Members of the board of directors or annual-meeting committees were more likely to disclose payments than others (86.0% vs 69.1%; P=0.009), and so were symposium presenters or instructional-course lecturers (87.0 vs 58.4%; P<0.001). Directly related payments were more likely to be disclosed than unrelated payments (79.3% vs 49.2%; P=0.008).

Patel 2018[45]	Study type Impact factor Specialty*	“Other” surgical subspecialties (including Cardiothoracic Surgery, Head and Neck, Neurosurgery, Vascular Surgery) were less likely to have discrepancies than general surgery (OR 0.61; 95% CI, 0.38 – 1.00; P=0.01).
Ross 2020[40]	Authorship order*	Authors listed last on a paper were found to have significantly more undeclared payments than first and middle authors (77% vs 47% vs 51%; P<0.0001).

*Factor was significantly associated with nondisclosure

Abbreviations: COI: conflicts-of-interest; CI: confidence interval; OR: odds ratio

Reported explanation for discrepant reporting of COI

One study investigated *explanations* for non-disclosure by administering a survey to physicians who had not fully disclosed COI in the final program of an annual meeting,[11] with a response rate of 39.6% (36 / 91). The most common explanations for nondisclosure were that payment were considered unrelated to the topic of the presentation (39%; 14 of 36), or that disclosure requirements were misunderstood (14%; 5 of 36). Other explanations include that the payment was disclosed, but mistakenly omitted from the annual-meeting program (11%; 4 of 36), that the disclosure process was handled by a co-author who failed to communicate disclosure requirements (8%; 3 of 36), or that the payment was unintentionally omitted from the disclosure statement (6%; 2 of 36). Another 3% (1 of 36) reported that the payment from industry was not large enough to be disclosed.

Relationship between undisclosed COI and study outcomes

Data concerning the of association unreported COI and research outcome was reported by three studies, but the results are conflicting.[45, 48, 50] One study found that studies with discrepancies between declared COI and actual COI were more likely to report positive outcomes when compared to those that had no discrepancies, even after adjusting for impact factor, surgical specialty, and study type (OR 3.21, 95%CI 1.81 – 5.70, P < 0.0001).[45] However, two studies reported that authors with any COI, regardless of whether disclosed or not, were significantly more likely to report positive outcomes.[48, 50] In fact, in one of these studies, manuscripts in which authors fully disclosed all COI had a higher odds of providing a favorable impression of the discussed product (12.4, 95% confidence interval 4.4–35.4, p<0.001).[48]

Risk of bias assessment

Figure 2 depicts the risk of bias assessments of the 40 included studies. Several studies did not use a wide-enough sample frame to address the study’s target population.[11, 26, 38, 46, 47, 52, 53] For example, some studies had a target population of all physicians but their sample frame only included a single specialty. However, our review included a variety of specialties in order to draw inferences about physicians in general. Another possible source for bias is that included studies seldom performed a sample size calculation, as all were observational and exploratory.

Discussion

Statement of principal findings

Our review identified 40 cross-sectional studies which examined the accuracy of self-reporting of financial COI by physicians. The evidence examined indicates a high prevalence of discrepancies in the reporting of financial COI among physicians across a range of academic settings and clinical specialties. Most undisclosed COI were those related to expenses such as food and beverage, or travel and lodging. Undisclosed payments accounted for 33% (95% confidence interval 12–58%) of the total payments received. The most common explanation for failure to disclose COI provided by physicians was that payments were “perceived” as unrelated to the presentation or article in question.[11] But in fact, a median of 45% of the non-disclosed payments from pharmaceutical companies or device manufacturers were directly or indirectly related to the published or presented academic work. We also found that smaller monetary amounts and payment relevance (to the article or presentation) are the most commonly reported predictors of nondisclosure amongst a variety of payment, author, article, and journal-related factors.

Strengths and weaknesses of the study

Strengths of our review include the robust search strategy, which involved a systematic search of three databases using a broad search strategy. We identified a large number of studies enabling us to characterize discrepancies in self-reported payments across multiple settings and disciplines. We were also able to stratify discrepancies across articles, authors, authorships, and payments in order to provide estimates of discrepant reporting at each of these levels.

There were several major limitations to our study. First, our exploratory meta-analysis combined data across studies to estimate the rate of discrepant reporting with more precision than is possible from a single study alone. However, the differences between the physician population and methodologies used for assessment of COI across studies resulted in high heterogeneity for pooled results. Most notably, the definition of COI employed by each of the studies varied in terms of the types and values of payments included. For example, not all studies considered food and beverage as a COI, and the threshold above which a payment was considered a COI was not

consistent. In addition, a large proportion of studies did not assess relevant disclosures. While this may explain the high rate of mismatch with industry reports, our study suggests that physicians are poor assessors of relevance. Thus, the results of the exploratory analyses should be interpreted with caution and largely serve to visually illustrate the range and variability between studies. There are also limitations to the “objective data sources” relied upon for disclosures by industry. Inconsistencies in these databases, which could represent under or over-reporting by industry, have been reported.[26] While physicians are able to review this data, a challenging payment dispute process may inhibit them from attempting to correct inaccuracies.[56] Moreover, with the exception of two studies from Denmark, our study is limited to physicians in the United States. Hence it does not include payments from foreign sponsors or payments to foreign physicians and may not be generalizable to other countries which do not mandate reporting of payments by industry. Nonetheless, given that many countries have made industry disclosures mandatory and regulated, we believe this is the most comprehensive source of all payment data for our analysis. Finally, there may be an element of publication bias. More specifically, studies that demonstrate a high discrepancy may be published in favour of studies with low discrepancies. However, the high heterogeneity found in our exploratory meta-analyses precluded a meaningful quantitative analysis of publication bias.

Strengths and weaknesses in relation to other studies

Our results verify and extend those reported by Wayant et al [57] who identified ten studies that examined, exclusively amongst authors of clinical practice guidelines, the truthfulness of the reporting by physicians of financial relationships with industry. Those authors identified a pooled accuracy of 18% between actual and reported financial COIs. Our review extends these findings by evaluating physician disclosure practices among authors of both CPGs and other publications, presenters of abstracts and papers at scientific meetings, and individuals organizing academic meetings. We further characterized discrepancies by examining putative factors that might be associated with nondisclosure.

Meaning of the study: possible explanations and implications for clinicians and policymakers

Putative explanations for the high rates of nondisclosure of financial COIs by physicians rely upon claims that guidelines specifying what is relevant to report are subjective and open to interpretation, although most guidelines are standardized to reduce variation and leave little room for authors to decide what relationships may be relevant to report. In 2009, a detailed disclosure form was introduced by the ICMJE, requiring all authors to disclose all relevant COI within the past 36 months, encouraging physicians to err on the side of over disclosure.[8] Our review found that the accuracy of disclosure was not associated with that journal’s disclosure requirements or its endorsement of ICMJE policy requirements[46], which may be related to variability of enforcement. Despite efforts to standardize the disclosure process, physicians may continue to

omit reporting relevant disclosures due to false convictions that their relationships with industry do not apply to their work.[11] Our meta-analysis found, however, that a significant proportion of discrepancies were related to the academic work in question, suggesting that physicians may not be the most accurate assessors of payment relevance.

The ICMJE form requires authors to specify all relationships with industry, regardless of the amount of compensation. While the amounts of unreported payments varied across studies, we found that smaller amounts were more likely to be unreported compared to larger payment amounts. In addition, general payments such as food and beverage, travel and lodging were most likely to go unreported. This is arguably due to a common perception that expenses for food or travel costs are unlikely to affect decision-making and may not have equivalent importance as payments for consulting or honoraria. However, the often-advanced idea that small payments from industry are unlikely to affect physician judgment in research or medical practice is not supported by the literature. By contrast it is clear that feelings of obligation and impulses toward reciprocity are not related to the size of a gift;[58, 59] small as well as larger gifts are associated with increased rates of prescribing brand-name medications.[60]

The findings of this systematic review and meta-analysis suggest that changes to COI disclosure policies beyond those required by the ICMJE are necessary in the interests of transparency, otherwise self-reported disclosure will continue to remain an empty panacea. We agree with calls to improve disclosure through enforced, structured reporting and processes to assess relevance.[61] One possible solution is for journals and guideline development organizations to provide authors with prepopulated disclosure forms with data extrapolated from public databases. By doing so, the bias associated with determining relevance on disclosure forms can be reduced. Authors should be provided an opportunity to confirm each COI, and provide justification for payments they consider inaccurate or irrelevant which can then be verified by an unbiased party. Ultimately, full transparency depends on moving away from entirely self-reported disclosures of payments from industry by physicians, and will require enhanced education on adequate disclosures of COI by academic institutions and stronger, well-enforced policies to address non-compliance—the violation of which result in tangible consequences. Physicians who are found to not disclose their relationships with industry should expect to face misconduct charges and academic sanctions.[62] While verifying each author’s disclosures may require significant time and effort by journal editors, the falsification of information that others rely on to assess that work should be an academic offence that is not tolerated.

Unanswered questions and future research

Currently, ICMJE policies require authors to only report COI within the past 36 months. However, further research is warranted to ascertain the length of time during which physicians are susceptible to industry influence after receiving funds. Future research should also investigate the

effectiveness of various COI disclosure policies. This would help better inform policies implemented by journals, guideline developing organizations, and academic institutions.

Conclusions

Physician self-reports of financial COI are highly discrepant with objective data sources reporting payments from industry. Stronger policies are required by journals and guideline development organizations to reduce reliance on physician self-reporting of financial COI and address non-compliance.

Declarations

Transparency declaration: We affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination declaration: We have reported whether we plan to disseminate the results to study participants and or patient organisations OR stated that dissemination to these groups is not possible/applicable.

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Authors contributions: CT developed the research question, performed the literature search, assisted with developing the search strategy, extracted the data and assessed risk of bias, and was a major contributor in writing the paper. AK developed the search strategy, completed screening and assessed risk of bias, and was a contributor in writing the paper. XL completed screening, extracted the data and assessed risk of bias, and was a contributor in writing the paper. AL completed all statistical analysis and was a contributor in writing the paper. ST assisted with the qualitative analysis and was a contributor in writing the paper. NO is the senior author and provided guidance throughout the process. All authors read and approved the final protocol.

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Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analysis flow diagram.

Figure 2. Risk of bias assessment of included studies using a modified Joanna Briggs Institute Critical Appraisal Checklist for studies reporting prevalence data.

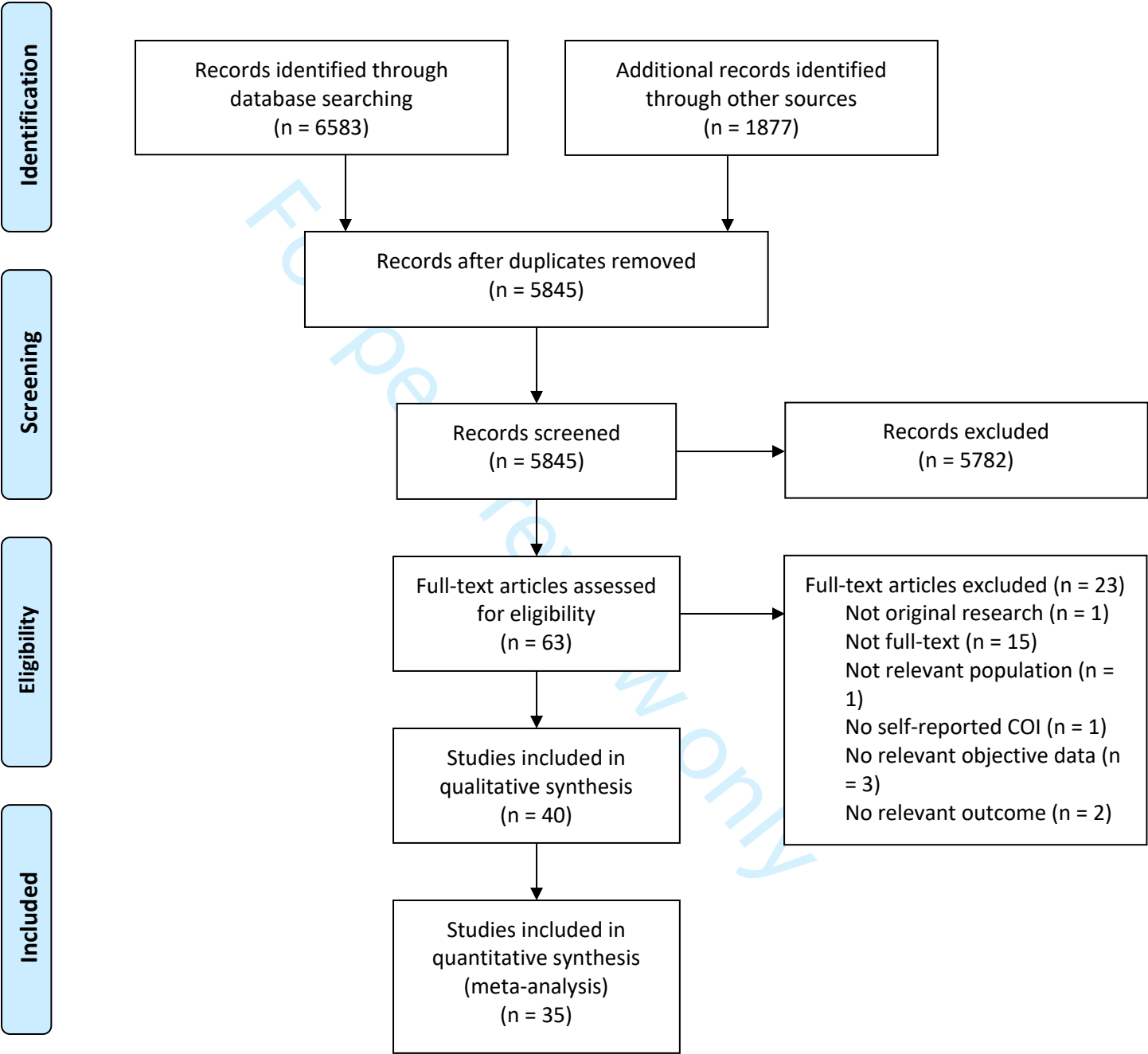
Appendix 1. Search strategy for Medline.

Appendix 2. Forest plot illustrating the number conflicts of interest (COI) discrepancies, defined as the number of unreported COI as a proportion of the total number of conflicts of interest. Panel A represents the COI discrepancies at the article level. Panel B represents the COI discrepancies at the payment level. Panel C represents the COI discrepancies at the authorship level. Panel D represents the COI discrepancies at the author level.

Appendix 3. Forest plot illustrating the reported funding discrepancies, defined as the amount of funding unreported as a proportion of the total funds received.



PRISMA 2009 Flow Diagram



































From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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Study	Checklist Item*							
	1	2	3	4	5	6	7	8
Ahmed 2018[22]								
Alhamoud 2016[26]								
Andreatos 2017[33]								
Bansal 2020[34]								
Bellomo 2020[36]								
Bindslev 2013[21]								
Boddapati 2018[35]								
Boyll 2019[51]								
Buerba 2013[14]								
Carlisle 2018[32]								
Checketts 2017[31]								
Cherla 2017[49]								
Cherla 2018a[48]								
Cherla 2018b[50]								
Chimonas 2011[46]								
Chopra 2020[52]								
Combs 2019[30]								

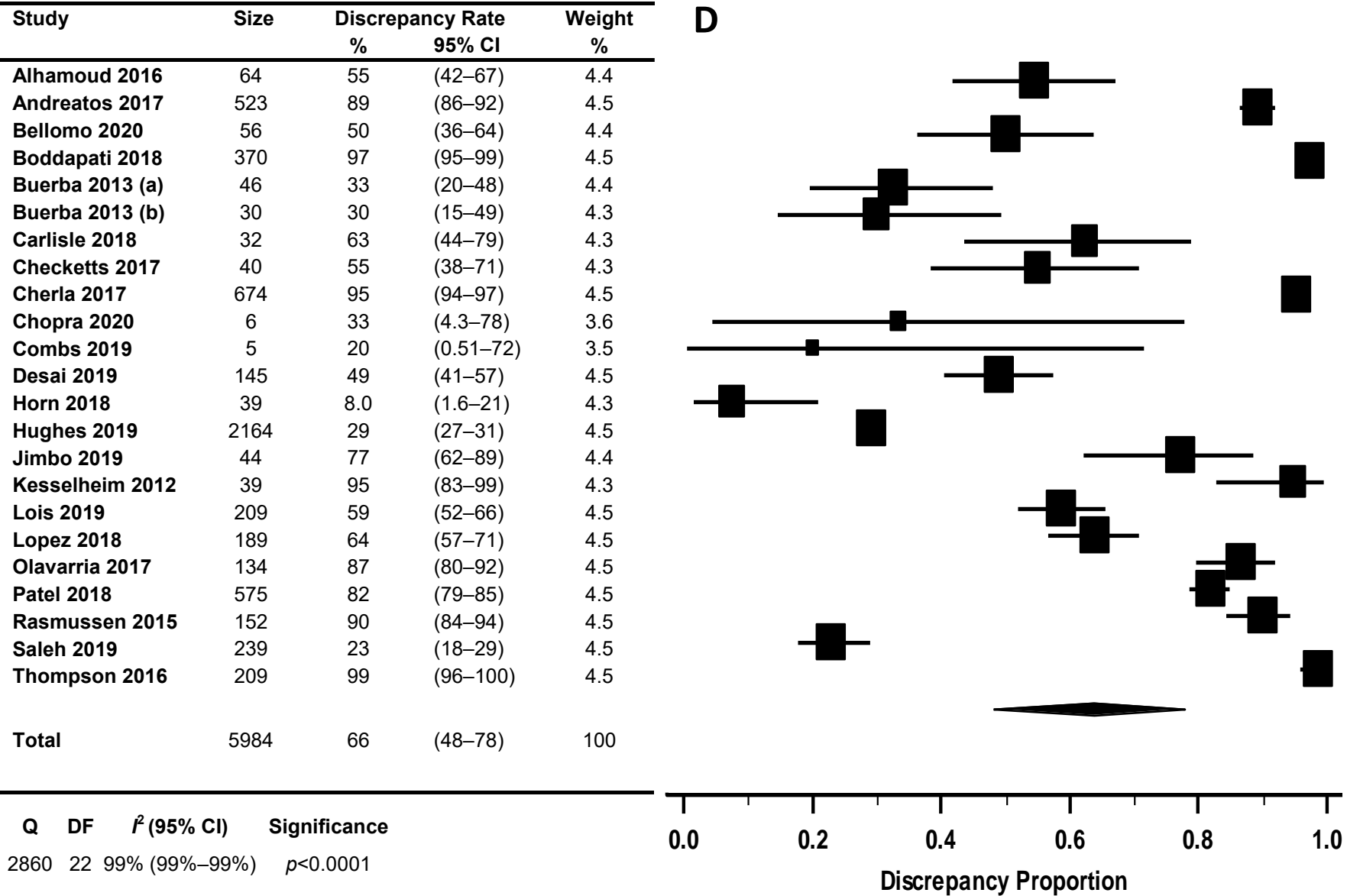
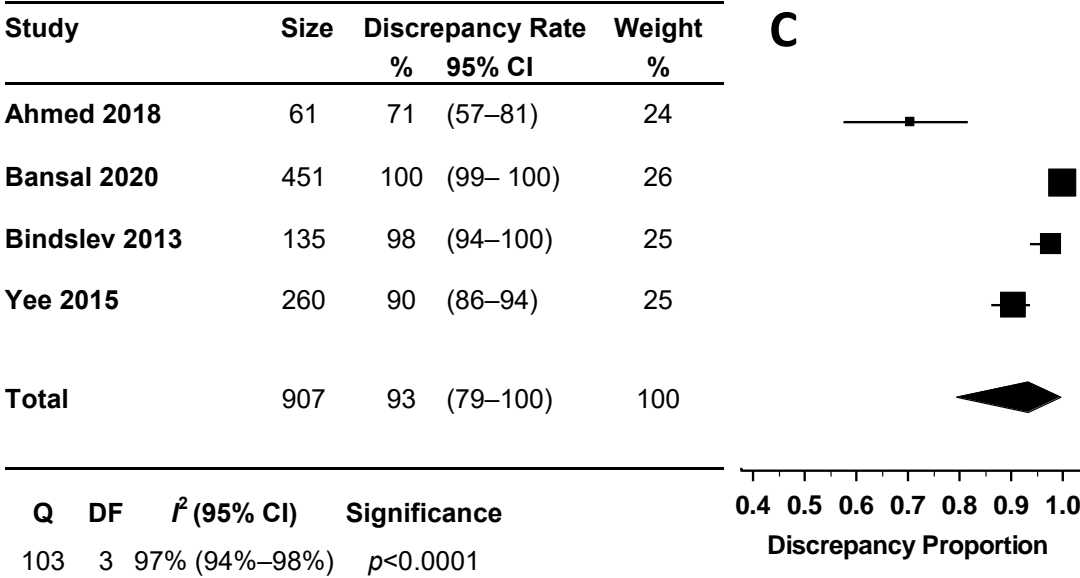
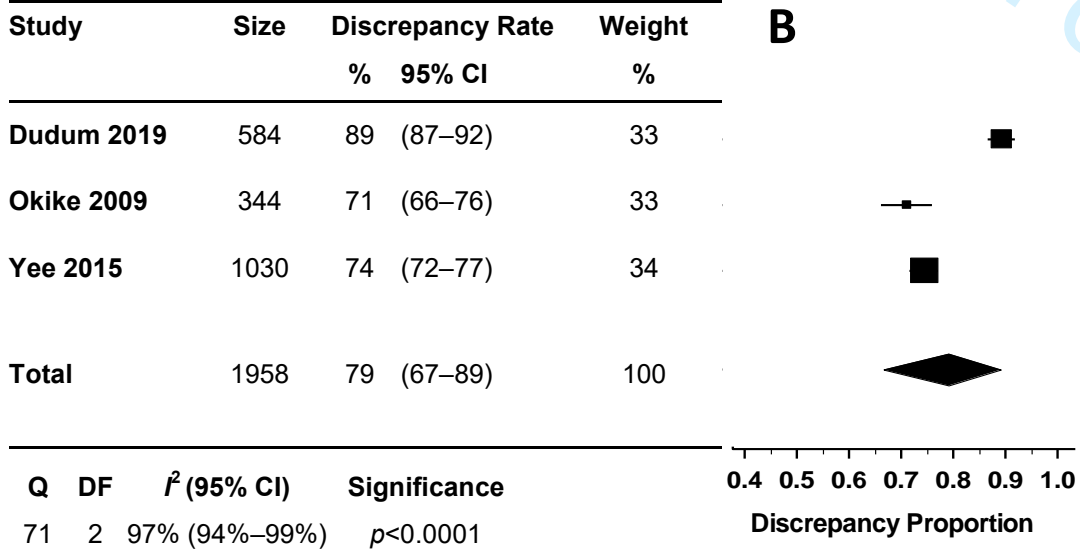
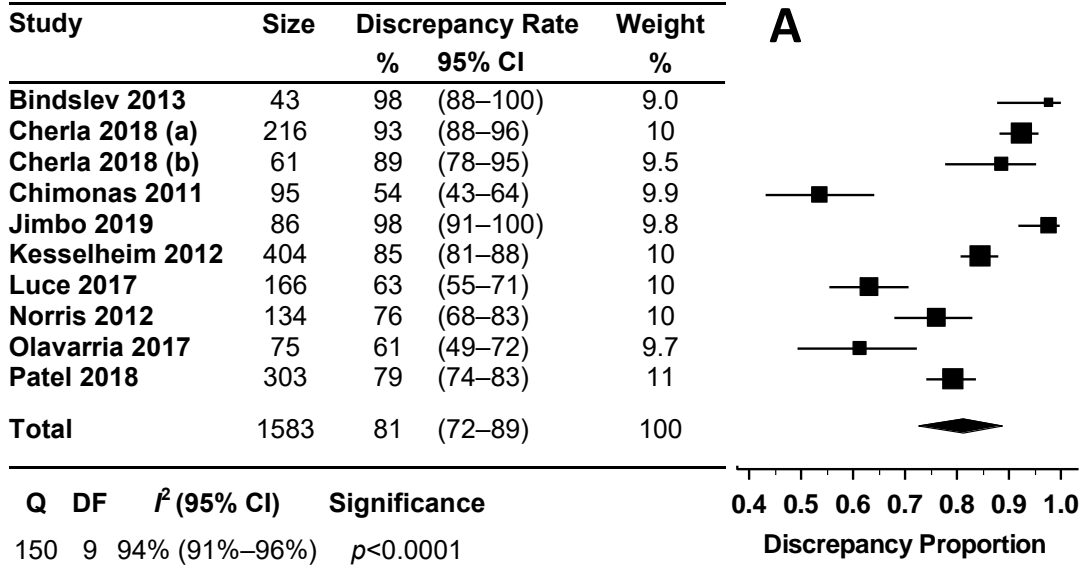
Desai 2019[23]								
Dudum 2019[27]								
Fu 2018[38]								
Garrett-Mayer 2020[55]								
Horn 2018[29]								
Hughes 2019[54]								
Janney 2019[47]								
Jimbo 2019[53]								
Kesselheim 2012[37]								
Lois 2019[25]								
Lopez 2018[15]; United States								
Luce 2017[42]; United States								
Norris 2012[13]								
Okike 2009[12]								
Olavarria 2017[41]								
Patel 2018[45]								
Rasmussen 2015[20]								
Ross 2020[40]								
Saleh 2019[28]								

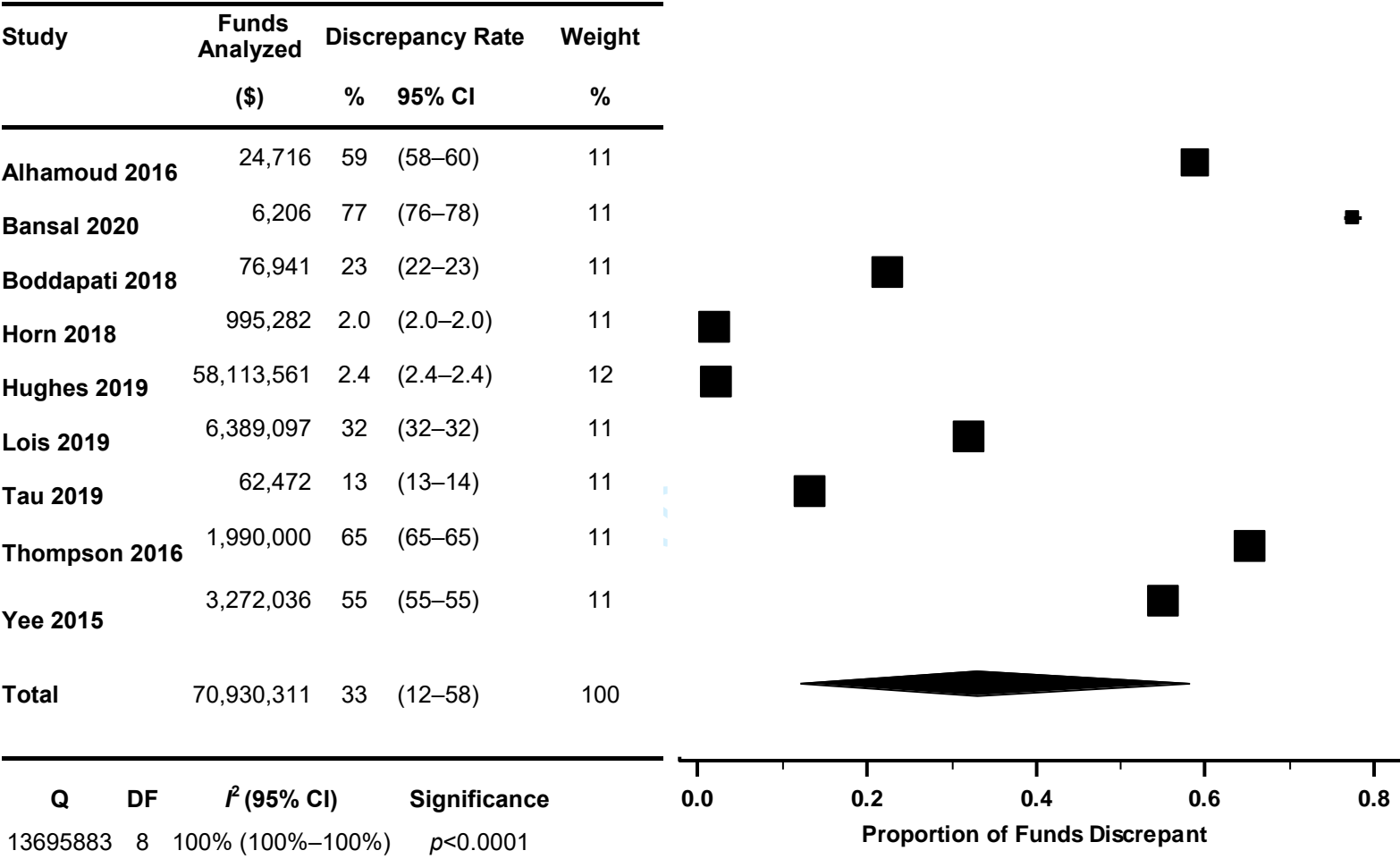
Somerson 2020[43]								
Tau 2019[39]								
Thompson 2016[24]								
Yee 2015[44]								

*Checklist Item:

1. Was the sample frame appropriate to address the target population?
2. Were study participants sampled in an appropriate way?
3. Was the sample size adequate?
4. Were the study subjects and the setting described in detail?
5. Was the data analysis conducted with sufficient coverage of the identified sample?
6. Were valid methods used for the identification of the objective payment data?
7. Were measurements conducted in a standard, reliable way for all participants?
8. Was there appropriate statistical analysis?

#	Searches
1	exp "conflict of interest"/
2	((conflict* or compet* or financial) adj1 (interest* or disclos*)).tw,kf.
3	exp Financial Support/es [Ethics]
4	(allergist* or anesthesiologist* or anesthetist* or cardiologist* or clinician* or dermatologist* or diabetologist* or doctor* or endocrinologist* or gastroenterologist* or general practitioner* or geriatrician* or gynecologist* or haematologist* or hospitalist* or internist* or medical resident* or neonatologist* or nephrologist* or neurologist* or neurosurgeon* or obstetrician* or oncologist* or ophthalmologist* or otolaryngologist* or pathologist* or pediatrician* or physician* or podiatrist* or psychiatrist* or pulmonologist* or radiographer or radiologist* or rheumatologist* or surgeon* or urologist*).tw,kf.
5	1 or 2 or 3
6	4 and 5







PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6



PRISMA 2009 Checklist

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	22
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	9
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	9
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	22
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	25

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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BMJ Open

Discrepancies in Self-Reported Financial Conflicts-of-Interest Disclosures by Physicians: Systematic Review

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Primary Subject Heading:	Ethics
Secondary Subject Heading:	Ethics
Keywords:	ETHICS (see Medical Ethics), GENERAL MEDICINE (see Internal Medicine), MEDICAL ETHICS

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Discrepancies in Self-Reported Financial Conflicts-of-Interest Disclosures by Physicians: Systematic Review

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Abstract

Background: There is a high prevalence of financial conflicts-of-interest (COI) between physicians and industry.

Objectives: To conduct a systematic review with meta-analysis examining the completeness of self-reported financial COI disclosures by physicians, and identify factors associated with non-disclosure.

Data sources: MEDLINE, Embase, and PsycInfo were searched for eligible studies up to April 2020 and supplemented with material identified in the references and citing articles.

Data extraction and synthesis: Data were independently abstracted by two authors. Data synthesis was performed via systematic review of eligible studies.

Main outcomes and measures: The proportion of discrepancies between physician self-reported disclosures and objective payment data was the main outcome. The proportion of discrepant funds and factors associated with non-disclosure were also examined.

Results: 40 studies were included. Most undisclosed COI were those related to food and beverage, or travel and lodging. While the most common explanation for failure to disclose was perceived irrelevance, a median of 45% of non-disclosed payments were directly or indirectly related to the work. A smaller monetary amount was the most commonly reported factor associated with nondisclosure. An attempt was made to pool results but there was high heterogeneity between studies across all five analyses ($I^2=94-99\%$). The pooled proportion of COI discrepancies at the article level was 81% (range: 54–98%; 95% Confidence Interval (CI): 72%–89%), 79% at the payment level (range: 71–89%; 95% CI: 67–89), 93% at the authorship level (range: 71–100%; 95% CI: 79–100%), and 66% at the author level (range: 8–99%; 95% CI: 48%–78%). The proportion of funds discrepant was 33% (range: 2–77%; 95% CI: 12–58%).

Conclusions: Physician self-reports of financial COI are highly discrepant with objective data sources reporting payments from industry. Stronger policies are required to reduce reliance on physician self-reporting of financial COI and address non-compliance.

Strengths and limitations of this study

- The study systematically reviewed the literature to characterize discrepancies in self-reported payments across multiple settings and disciplines.
- The results were stratified across different levels in order to provide more accurate estimates of discrepant reporting.
- The population and methodologies used for assessment of conflicts of interest are not the same across studies.
- Many of the objective data sources used in the included studies relied on disclosures by industry, which may have inconsistencies.
- The study is largely limited to physicians in the United States and may not be generalizable to other countries.

Background

Financial conflicts-of-interest (COI) between physicians and industry commonly occur, and are a longstanding area of public concern.[1, 2] They occur in situations where a person has a moral obligation to exercise judgment in another’s service and, at the same time, an interest tending to interfere with the proper exercise of judgment in that relationship. Under this definition “judgment” refers to intelligent activity requiring more than mechanical rule following; “interest” refers to personal financial benefit, family interest or any special influence or loyalty which could undermine the performance of one’s duty to exercise one’s judgment objectively.[3] Financial COI have the potential to undermine the integrity of medical research, education, and practice.[3, 4, 5] Considerable evidence indicates that financial COI may influence the conduct and reporting of research, increase the likelihood of research outcomes favoring the sponsor (usually the pharmaceutical or device industry).[1, 6] Additionally, financial COI may be associated with inappropriate prescribing patterns.[7]

Financial COI occur in situations in which there is transfer of payment from industry to physicians. This is independent of whether these payments are disclosed. The National Academy of Medicine, a US non-profit organization which is independent of government and provides policy recommendations for public health and science, asserts that accurate disclosures of conflicts of interest protect the integrity of professional judgment and preserve the public trust in physicians.[5] Over the past decade, many academic institutions and medical journals have adopted guidelines which guide disclosures of financial COI in a putative effort to increase transparency, encourage critical appraisal of research findings, and enable research into the effects of COI.[8] Unfortunately, disclosure has not been shown to eliminate bias.

While there has emerged credible criticism that disclosure is not a solution to the management of COI,[9, 10] financial COI disclosures have become a quintessential part of conducting and publishing research, delivering academic presentations and educating medical students at this time. Complicating the issue is that disclosure of financial COIs relies almost entirely on self-reporting by those benefiting from financial gain. There has traditionally been no means of verification of the correlation between payments received, and disclosure. Indeed many physicians have been reported to omit, or incompletely disclose relevant COI, even in situations in which guidelines require this disclosure,[2, 11-14] resulting in incorrect information provided to those reading, interpreting, or using the data reported. The extent of and factors associated with this under-reporting of financial COI by physicians may be less well studied than warranted by this important issue. To date, there has not been a systematic search of the literature identifying studies comparing actual and disclosed financial COI. Our study aims to systematically examine the literature on completeness of self-reported financial COI disclosures by physicians, and identify the factors associated with non-disclosure.

Methods

This systematic review was conducted according to the standards and guidelines established by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) and the fourth edition of the Joanna Briggs Institute Reviewer's Manual.[15, 16] Methods of the analysis and inclusion criteria were specified in advance and documented. Our protocol is publicly available (<https://osf.io/fzhd7>).

Eligibility Criteria

We included studies that sought to examine discrepancies between financial COI which were reported by physicians, and the objective data which documented payments from industry to the physicians as either the primary or secondary objective. We considered a discrepancy to be present if data provided information about relevant financial support that was not reported by the physicians themselves. We considered objective payment data to be any data that was not reported by physicians themselves. Comparisons between self-reported disclosures were not eligible for our study as these were not considered to be complete. We examined only original, peer-reviewed literature in the English language including cross-sectional analyses, prospective cohorts, and retrospective cohorts. Published conference posters and abstracts were not eligible for inclusion as we required full-text manuscripts to optimize the completeness of our data. Articles were excluded if they did not focus on physicians, did not assess COI involving payments from the pharmaceutical (or device manufacturing) industry, or if they did not have available an objective comparator. We reviewed studies that focused on disclosures in any setting, such as research publications, clinical practice guidelines, academic presentations, or conference committees.

Information Sources

We consulted a University of Toronto research librarian to help develop the search strategy. We searched Ovid MEDLINE (1946 – April 2020), Ovid EMBASE (1947 – April 2020), and PsycInfo (1806 – April 2020) using a combination of both MESH subject headings (exploded) and key words. Subject-specific search terms adapted from previously published systematic reviews on financial COI (“conflict of interest”, “financial support”, and “funding”) were combined with a filter to retrieve studies related to physicians.[6, 17, 18] The search strategy is included in Appendix 1. In addition, we reviewed the references of included papers and searched for studies that have cited these papers using SCOPUS.

Study Selection

Study selection was completed in duplicate by two independent, parallel reviewers (AK, XL) using title, abstract and full-text screening. Disagreements between reviewers were resolved

independently by a blinded third reviewer (CT). Covidence was used for both data management and screening.

Data Collection

To further refine extraction categories we developed, *a priori*, a data extraction sheet, and pilot-tested it on ten randomly selected studies we had included. Data were extracted in duplicate by two independent, parallel reviewers (CT, XL). Disagreements were resolved by discussion between the two reviewers and subsequent consultation with a third author (AK).

From each study, we extracted the clinical focus, study design, primary objective, sources of data collection, time of payments, how COI were defined, number and monetary amount of total COI, number and monetary amount of undisclosed COI, number of relevant undisclosed COI, types of undisclosed COI, factors associated with undisclosed COI, reasons for non-disclosure, and association of nondisclosure with study outcomes.

We assessed the risk of bias of each included study using a modified version of the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Studies Reporting Prevalence data. The JBI checklist is used to determine the extent to which a study has addressed the possibility of bias in its design, conduct and analysis. Individual studies are scored as either “Yes,” “No,” or “Unclear” for each checklist item. We considered a sample greater than 1000 to be adequate in the absence of an appropriate sample size calculation. The risk of bias assessment was done in duplicate by two independent, parallel reviewers (AK, XL). Disagreements were resolved by discussion between the two reviewers and subsequent consultation with a third author (CT).

Data Synthesis

The included studies were described and summarized by narrative synthesis. We also conducted an exploratory meta-analysis of the studies which reported the data necessary to compute the proportion of payments discrepant and the amount of funds discrepant.

Statistical Analyses and Outcomes

Our primary outcome was the proportion of COI which was discrepant: that is, the proportion in which objective documentation of funding had not been self-reported. Our secondary outcome was the proportion of funds discrepant: that is the amount of funds (US dollars) which had not been self-reported. Disclosures that were reported by physicians, but not reported by the objective data source, were not considered to be discrepancies in this study.

Data were stratified into four groups according to whether they described discrepancies among authorships, authors, articles, or payments. Refer to table 1 below to better understand how we use these terms. In each case, the proportion of COI identified as discrepant between self-reporting and objective was defined as the number undisclosed COI over the total number of COI.

Table 1. Definitions of groups used to stratify data.

Group	Definition	Example
Authorship	One instance of disclosure by one individual. One authorship may involve multiple transactions.	Sorting by authorship can involve identifying any discrepancies in COI reporting by one author in a single published work.
Author	A unique individual who can have more than one authorship. An author may be involved in multiple authorships.	Sorting by author can involve identifying any discrepancies in COI reporting by one author among a number of publications.
Article	A group of individuals with authorships for a single published work	Sorting by article involves identifying any discrepancies in COI reporting by any author of a single published work.
Payment	A single transaction between industry and authors.	Sorting by payment involves identifying any discrepancies in COI reporting by one individual for a single transaction.

Each payment was treated as equal regardless of the amount of funding or the amount discrepant. The proportion of funds identified as discrepant between self-reporting and objective data was defined as the undisclosed funds as a proportion of the funds recorded in the payment database. The proportion of COI identified as discrepant between self-reporting and objective data and the proportion of funds identified as discrepant between self-reporting and objective data were pooled in an exploratory meta-analysis and analyzed using a random-effects model. Exploratory analyses were performed to determine the degree of heterogeneity between studies and to quantitatively determine the proportion of COI and funds discrepant across studies. A random-effects model was used because of the expected methodological and sample heterogeneity between studies. The I^2 statistic was used to measure heterogeneity between studies and $p < 0.05$ was considered statistically significant. Statistical analysis was performed using MedCalc Statistical Software v19.2.6.[19]

Results

Search Results

Figure 1 illustrates the PRISMA flow diagram. Searches and other data sources provided a total of 8460 citations. After removing duplicates, 5845 studies remained. Of these, we discarded 5781 studies after reviewing the abstracts which indicated the papers did not meet the inclusion criteria. One additional study was discarded because the full text of the study was not available. We assessed the full text of the remaining 63 citations. We identified a total of 40 studies for inclusion in the systematic review, 12 of which were identified by searching reference lists and citing articles. Inter-rater reliability for study screening for titles/abstract and full-text screening was 99.5% and 91.2% respectively. The authors were in substantial agreement or better with a calculated Kappa of 0.77 and 0.81 respectively.

Characteristics of Included Studies

Table 2 summarizes the characteristics of the 40 studies included in this analysis. All studies had a cross-sectional design. Thirty-eight studies were conducted in the United States and two in Denmark.[20, 21] Six studies assessed disclosures from academic meetings[11, 13, 22, 23, 24, 25], ten assessed disclosures in clinical practice guidelines[21, 26, 27, 28, 29, 30, 31, 32, 33, 34], 22 assessed those in other publications[12, 14, 20, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54], and one assessed those in both an academic meeting and publications.[51] All studies examined self-reported disclosures by physician authors or presenters of academic work; three studies also reported disclosures by conference organizers.[11, 23, 24] Most studies examined disclosures of physicians conducting work within a common discipline; four examined disclosures of physicians across a variety of disciplines.[12, 20, 37, 39] Disclosures in surgical disciplines were most commonly investigated; eight studies focused on disclosures of physicians working in orthopedic surgery[11, 13, 38, 40, 43, 46, 47, 54], three of those working in plastic surgery[14, 42, 51], two of those working in otolaryngology[23, 29], two of those working in urology[32, 53], and three of those working in other surgical specialties.[24, 45, 48] Aside from one which used data from the United States Department of Justice investigations,[37] all studies used industry-reported payment data as the objective comparison; of these 39 studies reliant upon industry-reported payment data, 30 examined data from the Centers for Medicare and Medicaid Services' Open Payments Database (OPD)[12, 14, 23, 24, 25, 27, 28, 29, 30, 31, 32, 33, 34, 35, 38, 39, 40, 41, 42, 43, 44, 45, 47, 48, 49, 50, 51, 53, 54, 55], two studies used the ProPublica's Dollars for Docs database[26, 36], two studies used both of these sources[23, 52], two studies used the Danish Health and Medicines Authority's public disclosure list[20, 21], and three studies referenced the web pages of device manufacturers.[11, 13, 46] All included studies examined different data sets except two [11, 46] both of which examined the same data set involving five manufacturers of total hip and knee prosthesis in 2007. Most studies examined COI involving

relatively recent financial relationships; one study[37] examined relationships dating back to 1999. Two studies[49, 50] did not specify the time period studied.

Proportion of COI discrepant

As outlined above the included studies examined COI involving articles, authors, authorships, or payments. The majority of studies defined discrepancies as one or more undisclosed COI, but three studies considered a discrepancy to occur only when all COI were inaccurately disclosed by an author.[36, 47, 54]

An exploratory meta-analysis was attempted to summarize the studies that examined the accuracy of self-reported financial COI at the article, payment, authorship, and author level. However, heterogeneity of pooled data was high across all four levels examined with $I^2=94-99\%$. For completeness, we have reported the results of this analysis in Appendix 2. The pooled proportion of the 10 studies (1583 total articles pooled) reporting discrepancies at the article level was 81% (range: 54–98%; 95% Confidence Interval (CI): 72%–89%) (Appendix 2, Panel A). The pooled proportion of the three studies (1958 total payments pooled) reporting discrepancies at the payment level was 79% (range: 71–89%; 95% CI: 67–89) (Appendix 2, Panel B). The pooled proportion of the four studies (907 total authorships pooled) reporting discrepancy at the authorship level was 93% (range: 71–100%; 95% CI: 79–100%) (Appendix 2, Panel C). The pooled proportion of the 23 studies (5984 total authors pooled) reporting discrepancy at the author level was 66% (range: 8–99%; 95% CI: 48%–78%) (Appendix 2, Panel D).

Table 2. Characteristics of included studies.

Author Year; Country	Study Design	Focus of Research	Self-Disclosure Source	Objective Data Source	Level of Data	Time of Payments
Ahmed 2018[22]; United States	Cross-sectional	Radiation-oncology	Authors of presentations at academic meeting	OPD	Authorship	2013-2015
Alhamoud 2016[26]; United States	Cross-sectional	Cardiology	Authors of CPGs	DFD	Author	2009-2012

Andreatos 2017[33]; United States	Cross-sectional	Various disciplines	Authors of CPGs	OPD	Author	2013-2014
Bansal 2020[34]; United States	Cross-sectional	Gastroenterology	Authors of CPGs	OPD	Authorship	2013-2017
Bellomo 2020[36]; United States	Cross-sectional	Vascular	Authors of publications	DFD	Author	2013-2016
Bindslev 2013[21]; Denmark	Cross-sectional	Various disciplines	Authors of CPGs	Danish Health and Medicines Authority disclosure list	Article, Authorship	2007-2012
Boddapati 2018[35]; United States	Cross-sectional	Sports medicine	Authors of publications	OPD	Author	2014-2015
Boyll 2019[51]; United States	Cross-sectional	Plastic surgery	Authors of publications	OPD	Article, Author, Authorship	2013-2016
Buerba 2013[13]; United States	Cross-sectional	Spine surgery	Authors of presentations at academic meeting	Company web pages	Author	2010

Carlisle 2018[32]; United States	Cross-sectional	Urology	Authors of CPGs	OPD	Author	2012-2014
Checketts 2017[31]; United States	Cross-sectional	Dermatology	Authors of CPGs	OPD	Author	2013-2015
Cherla 2017[49]; United States	Cross-sectional	Pulmonology, hematology, orthopedics, cardiac surgery, otorhinolaryngology	Authors of publications	OPD	Article, Author	NR
Cherla 2018a[48]; United States	Cross-sectional	Surgery	Authors of publications	OPD	Article	2012-2016
Cherla 2018b[50]; United States	Cross-sectional	Ventral hernia	Authors of publications	OPD	Article	NR
Chimonas 2011[46]; United States	Cross-sectional	Orthopedics	Authors of publications	Company web pages	Article, Author	2017
Chopra 2020[52]; United States	Cross-sectional	Various disciplines	Authors of publications	OPD and DFD	Author	2013-2015
Combs 2019[30]; United States	Cross-sectional	Various disciplines	Authors of CPGs	OPD	Author, Payment	2014-2017

Desai 2019[23]; United States	Cross- sectional	ENT	Authors of presentatio ns at academic meeting	OPD and DFD	Author	2013-2015
Dudum 2019[27]; United States	Cross- sectional	Cardiology	Authors of CPGs	OPD	Author, Payment	2013-2017
Fu 2018[38]; United States	Cross- sectional	Orthopedic surgery	Authors of publication s	OPD	Authorshi p	2014-2015
Garrett- Mayer 2020[55]; United States	Cross- sectional	Oncology	Authors of presentatio ns at academic meeting and publication s	OPD	Author	2016-2017
Horn 2018[29]; United States	Cross- sectional	Otolaryngolog y	Authors of CPGs	OPD	Author	2013-2016
Hughes 2019[54]; United States	Cross- sectional	Orthopedic surgery/sports medicine	Authors of presentatio ns at academic meeting	OPD	Author	2015
Janney 2019[47]; United States	Cross- sectional	Orthopedic surgery	Authors of publication s	OPD	Authorshi p	2013-2016

Jimbo 2019[53]; United States	Cross-sectional	Urology	Authors of publications	OPD	Article, Author	2013-2016
Kesselheim 2012[37]; United States	Cross-sectional	Various disciplines	Authors of publications	United States Department of Justice investigations	Article, Author	1999-2007
Lois 2019[25]; United States	Cross-sectional	Gastroenterology	Authors of presentations at academic meeting	OPD	Author	2017
Lopez 2018[14]; United States	Cross-sectional	Plastic surgery	Authors of publications	OPD	Author	2013
Luce 2017[42]; United States	Cross-sectional	Plastic surgery	Authors of publications	OPD	Article	2015
Norris 2012[12]; United States	Cross-sectional	Various disciplines	Authors of publications	DFD	Article	2009-2010
Okike 2009[11]; United States	Cross-sectional	Orthopedic surgery	Authors of presentations at academic meeting	Company web pages	Payment	2007

Olavarria 2017[41]; United States	Cross- sectional	Ventral hernias	Authors of publication s	OPD	Article, Author	2012-2014
Patel 2018[45]; United States	Cross- sectional	Robotic surgery	Authors of publication s	OPD	Article, Author	2013-2014
Rasmusse n 2015[20]; Denmark	Cross- sectional	Various disciplines	Authors of publication s	Danish Health and Medicines Authority's public disclosure list	Author	2010-2013
Ross 2020[40]; United States	Cross- sectional	Hand surgery	Authors of publication s	OPD	Author, Authorshi p	2014-2016
Saleh 2019[28]; United States	Cross- sectional	Oncology	Authors of CPGs	OPD	Author	2013-2017
Somerson 2020[43]; United States	Cross- sectional	Orthopedic surgery	Authors of publication s	OPD	Authorshi p	2015-2016
Tau 2019[39]; United States	Cross- sectional	Various disciplines	Authors of publication s	OPD	Author	2013-2015
Thompso n 2016[24];	Cross- sectional	Obstetrics/Gy necology	Authors of presentatio ns at	OPD	Author	2014

United States			academic meeting			
Yee 2015[44]; United States	Cross-sectional	Ophthalmology	Authors of publications	OPD	Authorship, Payment	2013

Abbreviations: CPG: Clinical Practice Guideline; OPD: Dollars For Docs (ProPublica); Open Payments Database (Centers for Medicare and Medicaid Services)

Relevance of discrepant COI

Nine studies reported the proportion of relevant discrepancies.[8, 11, 14, 20, 24, 34, 40, 42, 48] Discrepancies were reported as being considered relevant if the payments provided were directly, or indirectly, related to the topic of the presentation, clinical practice guidelines, or another publication. Because only nine studies reported these data, and each had examined discrepancies at a different level, we elected to not pool this outcome. The proportion of relevant discrepancies ranges from 6% to 99%. The median proportion of relevant discrepancies is 45%. There is considerable heterogeneity across studies.

Proportion of funds (of the total funds reported) that were discrepantly reported

Nine studies reported the proportion of total amounts which were discrepantly reported. However, similar to the proportion of COI discrepant, there was high heterogeneity between studies (I²=100%). The exploratory analysis that pools the proportion of nine studies (\$70,930,311 total funds pooled) reporting funding discrepancies are reported in Appendix 3. The pooled proportion of total amounts which were discrepant was 33% (range: 2–77%; 95% CI:12–58%).

Types of COI that were discrepantly reported

Specific types of financial COI were reported as undisclosed in nine studies. These were similar across studies.[22, 27, 28, 31, 34 35, 38, 43, 55] The most common category of undisclosed COI was general payments. According to the payment databases, general payments include food and beverage, travel and lodging, consulting, royalties and licenses, non-consulting services (including serving as faculty or speaker at an event other than continuing education), payments for education, speaker and faculty fees, and honoraria.[27, 34, 35, 38, 43, 55] Within this category, food and beverage were identified by three studies as among the most frequently undisclosed.[38, 43, 55] Two studies identified travel and lodging[38, 55], two identified consulting and speaking[22, 27],

and one identified non-consulting services (including serving as faculty or speaker at an event other than continuing education) as the most commonly undisclosed.[27] Two studies identified research payments as the most commonly undisclosed[22, 28], and another two studies identified them as commonly undisclosed.[34, 35]

Factors associated with discrepant reporting

A total of 15 out of 40 studies reported factors that are associated with discrepant reporting.[11, 13, 14, 22, 26, 33, 34, 35, 37, 40, 45, 46, 47, 49, 51] We conducted a narrative summary of these factors. Table 3 summarizes the results of each study reporting factors that were associated with discrepant reporting of financial COIs. We organized factors into four themes: factors related to author characteristics (e.g., academic affiliation), payment characteristics (e.g., amount of the payment from industry), article characteristics (e.g., level/hierarchy of evidence, such as systematic review versus commentary), and journal characteristics (e.g., impact factor). Of these, author and payment were the most commonly reported factors that were associated with discrepant reporting.

Three studies examined the influence of an author’s gender in discrepant reporting.[22, 34, 35] There were no consistent result regarding the outcomes. Six studies examined whether the position of an author on a scientific article influenced discrepant reporting.[34, 35, 37, 40, 46, 51] The data concerning author position was conflicting. Some studies found that prominent (first, last, or sole) authors were associated with discrepant reporting, while other studies found that other (middle) authors were associated with discrepant reporting. Two studies reported no association across authorship positions.[34, 37]

Other author-related factors include an affiliation with an academic institution, the physician specialty, and physician role at an academic meeting (e.g., organizer vs attendee). Two studies identified the influence of author affiliations on undisclosed payments;[14, 34] both reported that authors with academic affiliation were significantly more likely to have undisclosed payments compared to those without. One study reported that physician’s roles are associated with reporting behavior.[11] At one academic meeting, physicians who did not serve as board members or committee members, or who were not symposium presenters or instructional-course lecturers at the annual meeting were less likely to disclose. Four studies reported the associations between physician specialty and discrepant reporting.[33, 37, 45, 49] Three of these studies found an association[33, 45, 49]; one found no difference among specialties[37]. Patel (2018) reported that general surgeons were more likely to have discrepant reporting than those in other surgical specialties.[45] Cherla (2017) found that manuscripts related to hematology exhibited the highest discrepant reporting, while manuscripts related to otolaryngology were associated with the lowest rates.[49] Andreatos (2017) reported that authors of guidelines in general

medicine, orthopedics, trauma, pulmonology, gastroenterology, and radiology had significantly higher rates of discrepant reporting than did authors of guidelines in other specialties.[33]

Six studies reported on the association of the value of payments that were not disclosed.[11, 13, 14, 26, 33, 35] Five found that authors who received smaller total payments or individual payments of lesser value were associated with discrepant reporting [11, 13, 14, 26, 35] Studies differed in what was reported to be considered “significant” amounts, from \$500[14], \$10,000[11, 26], \$100,000[11, 13], to \$500,000.[35] The sixth study was the only one to report no statistically significant association between discrepant reporting and the value of the payments involved.[33]

Five studies commented on other payment-related factors.[11, 14, 33, 35, 46] One study found that payments made to a group or organization were more likely to be undisclosed when compared to payments made to an individual physician.[11] Additionally, when payments did not include an in-kind component they were less likely to be reported.[11] Payments that were unrelated to the topic of the presentation or article were more likely to be undisclosed than directly or indirectly related payments.[11, 14, 46] However, not all payment types were equally likely to be unreported. “General payments” (such as food and beverage, travel and lodging) were more likely to be incompletely or inaccurately reported than “research payments”.[33]

Three studies commented on article-level factors associated with discrepancies.[35, 37, 45] One study found that when stratified by the level of evidence, authors of papers of higher levels of evidence (level of evidence ≥ 1) were significantly more likely to have discrepancies than those authors of papers of lower levels of evidence.[35, 37] Another study found that there was no difference between comparative (observational studies, randomized controlled studies or meta-analyses/systematic reviews) and non-comparative studies (case series, technique description or editorials/comments).[45] Additionally, article citation index per year since publication was not associated with adequacy of disclosure.[37]

Three studies described the association of journal characteristics with discrepant reporting.[37, 45, 46] Two studies found no statistically significant association with journal impact factor.[37, 45] Moreover, one study found that the accuracy of disclosures did not vary with the strength of journals’ disclosure policies, and there was no association between a journal’s endorsement of specific International Committee of Medical Journal Editors (ICMJE) policy recommendations, and discrepant reporting.[46]

Table 3. Results of studies investigating factors associated with discrepant reporting.

Study	Factors Evaluated	Significant Results
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Ahmed 2018[22]	At least one disclosure* Duration of presentation Sex* Word count Year of presentation Words per second (spoken during presentation)*	On univariable analysis, having at least one disclosure (OR, 2.62; 95% CI, 1.02-5.24) and male sex (OR, 3.76; 95% CI, 1.45-12.8) were associated with having a discrepancy. On multivariable regression, only the number of words per second was correlated to having a discrepancy (OR, 1.08; 95% CI, 1.01-1.80).
Alhamoud 2016[26]	Payment amount*	Payments ≥\$10,000 were 2.8 times more likely to be reported than modest or no payments (P=0.001).
Andreatos 2017[33]	Specialty* Type of payment* Total payment value	Authors of general medicine (P=0.02), orthopedics/ trauma (P=0.01), pulmonology (P=0.02), gastroenterology (P=0.02), and radiology (P=0.03) guidelines had significantly less accurate COI disclosures compared to other specialties. Authors were significantly less likely to inaccurately report “research payments” compared to “general payments” (75.5% vs 87.3%; P=0.02).
Bansal 2020[34]	Sex* Academic affiliation* Authorship order	Male authors (odds ratio, 2.23; 95% confidence interval, 1.47-3.39) and academically affiliated authors (odds ratio, 8.87; 95% confidence interval, 5.57-14.13) were significantly more likely to have undeclared payments (P<0.001).

Boddapati 2018[35]	Payment amount* Authorship order* Sex* Level of evidence* Type of payment*	Authors with total payments >\$500,000 were less likely to be discrepant than those earning <\$10,000 (16.1% vs 85.3%; $P<0.001$). First authors had a lower percentage of payment values with discrepancy versus middle authors (13.8% vs 31.9%; $P=0.001$). Men had a lower percentage of payment values with discrepancy as compared with women (22.3% vs 95.3%; $P<0.001$). The discrepancy rate was lowest in the level of evidence 1 subgroup as compared with the other groups, such as level of evidence 2 (75.0% vs 90.3%; $P=0.013$). Authors were least discrepant in general payments compared to research and ownership payments (17.2% vs 32.7% vs 47.5%; $P<0.001$).
Boyll 2019[51]	Authorship order*	A middle author is less likely to have discrepancies than the first or last author (OR, 3.593; 95% CI, 1.211-10.657; $P=0.0212$).
Buerba 2013[13]	Payment amount*	Those who received payments <\$100,000 from Medtronic were more likely to have discrepancies in their disclosures than those who received payments >\$100,000 ($P=0.009$).
Cherla 2017[49]	Specialty*	Between the medical and surgical published literature, the discordance rate for manuscripts differed significantly (71.5% vs 60.7%; $P=0.01$). Hematology manuscripts exhibited the highest incomplete disclosure rate while Otorhinolaryngology manuscripts showed the lowest (75.0% vs 42.0%; $P<0.001$).
Chimonas 2011[46]	Authorship order* Payment relatedness* Journal policy	First, sole, or senior authors were more likely to disclose than middle authors (54% vs 32%; $P=0.03$). Articles related to company payments were more likely to disclose compared to unrelated payments (50% vs 11%; $P=0.04$).

Janney 2019[47]	Year of publication	N/A
Kesselheim 2012[37]	Type of article* Specialty Authorship order Journal impact factor Article citation index	The researchers found that commentaries were significantly less likely to have adequate disclosure compared to articles reporting studies or trials (OR 0.10; 95% CI 0.02-0.67; P=0.02).
Lopez 2018[14]	Academic affiliation* Payment relatedness* Payment amount*	Nonacademic authors were 6.25 times more likely to disclose COI compared with authors with an academic affiliation (P<0.0001). Authors who received \$500 or more in transactions of value were 9.09 times more likely to disclose COI compared with authors who received less than \$200 (P<0.0001). Authors whose COI was related to the topic of their article were 2.75 times more likely to disclose conflicts of interest compared with authors whose COI was unrelated to the topic of their article (P<0.0001).
Okike 2009[11]	Payment amount* Payment made to an individual physician* Payment with in-kind component* Physician role* Payment relatedness*	Payments were more likely to have been disclosed if they exceeded \$10,000 than if they did not (64.4% vs 42.9%; P<0.001), were directed toward an individual physician rather than a company or organization (78.1% vs 45.9%; P=0.04), or included an in-kind component (79.0% vs 46.3%; P=0.002). Members of the board of directors or annual-meeting committees were more likely to disclose payments than others (86.0% vs 69.1%; P=0.009), and so were symposium presenters or instructional-course lecturers (87.0 vs 58.4%; P<0.001). Directly related payments were more likely to be disclosed than unrelated payments (79.3% vs 49.2%; P=0.008).

Patel 2018[45]	Study type Impact factor Specialty*	“Other” surgical subspecialties (including Cardiothoracic Surgery, Head and Neck, Neurosurgery, Vascular Surgery) were less likely to have discrepancies than general surgery (OR 0.61; 95% CI, 0.38 – 1.00; P=0.01).
Ross 2020[40]	Authorship order*	Authors listed last on a paper were found to have significantly more undeclared payments than first and middle authors (77% vs 47% vs 51%; P<0.0001).

*Factor was significantly associated with nondisclosure

Abbreviations: COI: conflicts-of-interest; CI: confidence interval; OR: odds ratio

Reported explanation for discrepant reporting of COI

One study investigated *explanations* for nondisclosure by administering a survey to physicians who had not fully disclosed COI in the final program of an annual meeting,[11] with a response rate of 39.6% (36 / 91). The most common explanations for nondisclosure were that payment were considered unrelated to the topic of the presentation (39%; 14 of 36), or that disclosure requirements were misunderstood (14%; 5 of 36). Other explanations include that the payment was disclosed, but mistakenly omitted from the annual-meeting program (11%; 4 of 36), that the disclosure process was handled by a co-author who failed to communicate disclosure requirements (8%; 3 of 36), or that the payment was unintentionally omitted from the disclosure statement (6%; 2 of 36). Another 3% (1 of 36) reported that the payment from industry was not large enough to be disclosed.

Relationship between undisclosed COI and study outcomes

Data concerning the association of unreported COI and research outcome was reported by three studies, but the results are conflicting.[45, 48, 50] One study found that studies with discrepancies between declared COI and actual COI were more likely to report positive outcomes when compared to those that had no discrepancies, even after adjusting for impact factor, surgical specialty, and study type (OR 3.21, 95%CI 1.81 – 5.70, P < 0.0001).[45] However, two studies reported that authors with any COI, regardless of whether disclosed or not, were significantly more likely to report positive outcomes.[48, 50] In fact, in one of these studies, manuscripts in which authors fully disclosed all COI had a higher odds of providing a favorable impression of the discussed product (12.4, 95% confidence interval 4.4–35.4, p<0.001).[48]

Risk of bias assessment

Figure 2 depicts the risk of bias assessments of the 40 included studies. Several studies did not use a wide-enough sample frame to address the study’s target population.[11, 26, 38, 46, 47, 52, 53] For example, some studies had a target population of all physicians but their sample frame only included a single specialty. However, our review included a variety of specialties in order to draw inferences about physicians in general. Another possible source for bias is that included studies seldom performed a sample size calculation, as all were observational and exploratory.

Discussion

Statement of principal findings

Our review identified 40 cross-sectional studies which examined the accuracy of self-reporting of financial COI by physicians. The evidence examined indicates a high prevalence of discrepancies in the reporting of financial COI among physicians across a range of academic settings and clinical specialties. Most undisclosed COI were those related to expenses such as food and beverage, or travel and lodging. Undisclosed payments accounted for 33% (95% confidence interval 12–58%) of the total payments received. The most common explanation for failure to disclose COI provided by physicians was that payments were “perceived” as unrelated to the presentation or article in question.[11] But in fact, a median of 45% of the non-disclosed payments from pharmaceutical companies or device manufacturers were directly or indirectly related to the published or presented academic work. We also found that smaller monetary amounts and payment relevance (to the article or presentation) are the most commonly reported predictors of nondisclosure amongst a variety of payment, author, article, and journal-related factors.

Strengths and weaknesses of the study

Strengths of our review include the robust search strategy, which involved a systematic search of three databases using a broad search strategy. We identified a large number of studies enabling us to characterize discrepancies in self-reported payments across multiple settings and disciplines. We were also able to stratify discrepancies across articles, authors, authorships, and payments in order to provide estimates of discrepant reporting at each of these levels.

There were several major limitations to our study. First, our exploratory meta-analysis combined data across studies to estimate the rate of discrepant reporting with more precision than is possible from a single study alone. However, the differences between the physician population and methodologies used for assessment of COI across studies resulted in high heterogeneity for pooled results. Most notably, the definition of COI employed by each of the studies varied in terms of the types and values of payments included. For example, not all studies considered food and beverage as a COI, and the threshold above which a payment was considered a COI was not

consistent. In addition, a large proportion of studies did not assess relevant disclosures. While this may explain the high rate of mismatch with industry reports, our study suggests that physicians are poor assessors of relevance. Thus, the results of the exploratory analyses should be interpreted with caution and largely serve to visually illustrate the range and variability between studies. There are also limitations to the “objective data sources” relied upon for disclosures by industry. Inconsistencies in these databases, which could represent under or over-reporting by industry, have been reported.[26] While physicians are able to review this data, a challenging payment dispute process may inhibit them from attempting to correct inaccuracies.[56] Moreover, with the exception of two studies from Denmark, our study is limited to physicians in the United States. Hence it does not include payments from foreign sponsors or payments to foreign physicians and may not be generalizable to other countries which do not mandate reporting of payments by industry. Nonetheless, given that many countries have made industry disclosures mandatory and regulated, we believe this is the most comprehensive source of all payment data for our analysis. Finally, there may be an element of publication bias. More specifically, studies that demonstrate a high discrepancy may be more likely to be published than studies with low discrepancies. However, the high heterogeneity found in our exploratory meta-analyses precluded a meaningful quantitative analysis of publication bias.

Strengths and weaknesses in relation to other studies

Our results verify and extend those reported by Wayant et al [57] who identified ten studies that examined, exclusively amongst authors of clinical practice guidelines, the truthfulness of the reporting by physicians of financial relationships with industry. Those authors identified a pooled accuracy of 18% between actual and reported financial COIs. Our review extends these findings by evaluating physician disclosure practices among authors of both CPGs and other publications, presenters of abstracts and papers at scientific meetings, and individuals organizing academic meetings. We further characterized discrepancies by examining putative factors that might be associated with nondisclosure.

Meaning of the study: possible explanations and implications for clinicians and policymakers

Putative explanations for the high rates of nondisclosure of financial COIs by physicians rely upon claims that guidelines specifying what is relevant to report are subjective and open to interpretation, although most guidelines are standardized to reduce variation and leave little room for authors to decide what relationships may be relevant to report. In 2009, a detailed disclosure form was introduced by the ICMJE, requiring all authors to disclose all relevant COI within the past 36 months, encouraging physicians to err on the side of over disclosure.[8] Our review found that the accuracy of disclosure was not associated with that journal’s disclosure requirements or its endorsement of ICMJE policy requirements[46], which may be related to variability of

enforcement. Despite efforts to standardize the disclosure process, physicians may continue to omit reporting relevant disclosures due to false convictions that their relationships with industry do not apply to their work.[11] Our meta-analysis found, however, that a significant proportion of discrepancies were related to the academic work in question, suggesting that physicians may not be the most accurate assessors of payment relevance.

The ICMJE form requires authors to specify all relationships with industry, regardless of the amount of compensation. While the amounts of unreported payments varied across studies, we found that smaller amounts were more likely to be unreported compared to larger payment amounts. In addition, general payments such as food and beverage, travel and lodging were most likely to go unreported. This is arguably due to a common perception that expenses for food or travel costs are unlikely to affect decision-making and may not have equivalent importance as payments for consulting or honoraria. However, the often-advanced idea that small payments from industry are unlikely to affect physician judgment in research or medical practice is not supported by the literature. By contrast it is clear that feelings of obligation and impulses toward reciprocity are not related to the size of a gift;[58, 59] small as well as larger gifts are associated with increased rates of prescribing brand-name medications.[60]

The findings of this systematic review and meta-analysis suggest that changes to COI disclosure policies beyond those required by the ICMJE are necessary in the interests of transparency, otherwise self-reported disclosure will continue to remain an empty panacea. We agree with calls to improve disclosure through enforced, structured reporting and processes to assess relevance.[61] One possible solution is for journals and guideline development organizations to provide authors with prepopulated disclosure forms with data extrapolated from public databases. By doing so, the bias associated with determining relevance on disclosure forms can be reduced. Authors should be provided an opportunity to confirm each COI, and provide justification for payments they consider inaccurate or irrelevant which can then be verified by an unbiased party. Ultimately, full transparency depends on moving away from entirely self-reported disclosures of payments from industry by physicians, and will require enhanced education on adequate disclosures of COI by academic institutions and stronger, well-enforced policies to address non-compliance—the violation of which result in tangible consequences. Physicians who are found to not disclose their relationships with industry should expect to face misconduct charges and academic sanctions.[62] While verifying each author’s disclosures may require significant time and effort by journal editors, the falsification of information that others rely on to assess that work should be an academic offence that is not tolerated.

Unanswered questions and future research

Currently, ICMJE policies require authors to only report COI within the past 36 months. However, further research is warranted to ascertain the length of time during which physicians are susceptible

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3 to industry influence after receiving funds. Future research should also investigate the
4 effectiveness of various COI disclosure policies. This would help better inform policies
5 implemented by journals, guideline developing organizations, and academic institutions.
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7

8 *Conclusions*

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11 Physician self-reports of financial COI are highly discrepant with objective data sources reporting
12 payments from industry. Stronger policies are required by journals and guideline development
13 organizations to reduce reliance on physician self-reporting of financial COI and address non-
14 compliance.
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Declarations

Transparency declaration: We affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination declaration: We have reported whether we plan to disseminate the results to study participants and or patient organisations OR stated that dissemination to these groups is not possible/applicable.

Ethics approval and consent to participate: Not applicable

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Availability of data and materials: No additional data available.

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Patient and Public Involvement: It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

Authors contributions: CT developed the research question, performed the literature search, assisted with developing the search strategy, extracted the data and assessed risk of bias, and was a major contributor in writing the paper. AK developed the search strategy, completed screening and assessed risk of bias, and was a contributor in writing the paper. XL completed screening, extracted the data and assessed risk of bias, and was a contributor in writing the paper. AL completed all statistical analysis and was a contributor in writing the paper. ST assisted with the narrative synthesis and was a contributor in writing the paper. NO is the senior author and provided guidance throughout the process. All authors read and approved the final protocol.

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from Western University and is a senior medical student at the University of Toronto. ST received a BMSc from Western University and is a dentistry student at the University of Toronto.

For peer review only

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Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analysis flow diagram.

Figure 2. Risk of bias assessment of included studies using a modified Joanna Briggs Institute Critical Appraisal Checklist for studies reporting prevalence data.

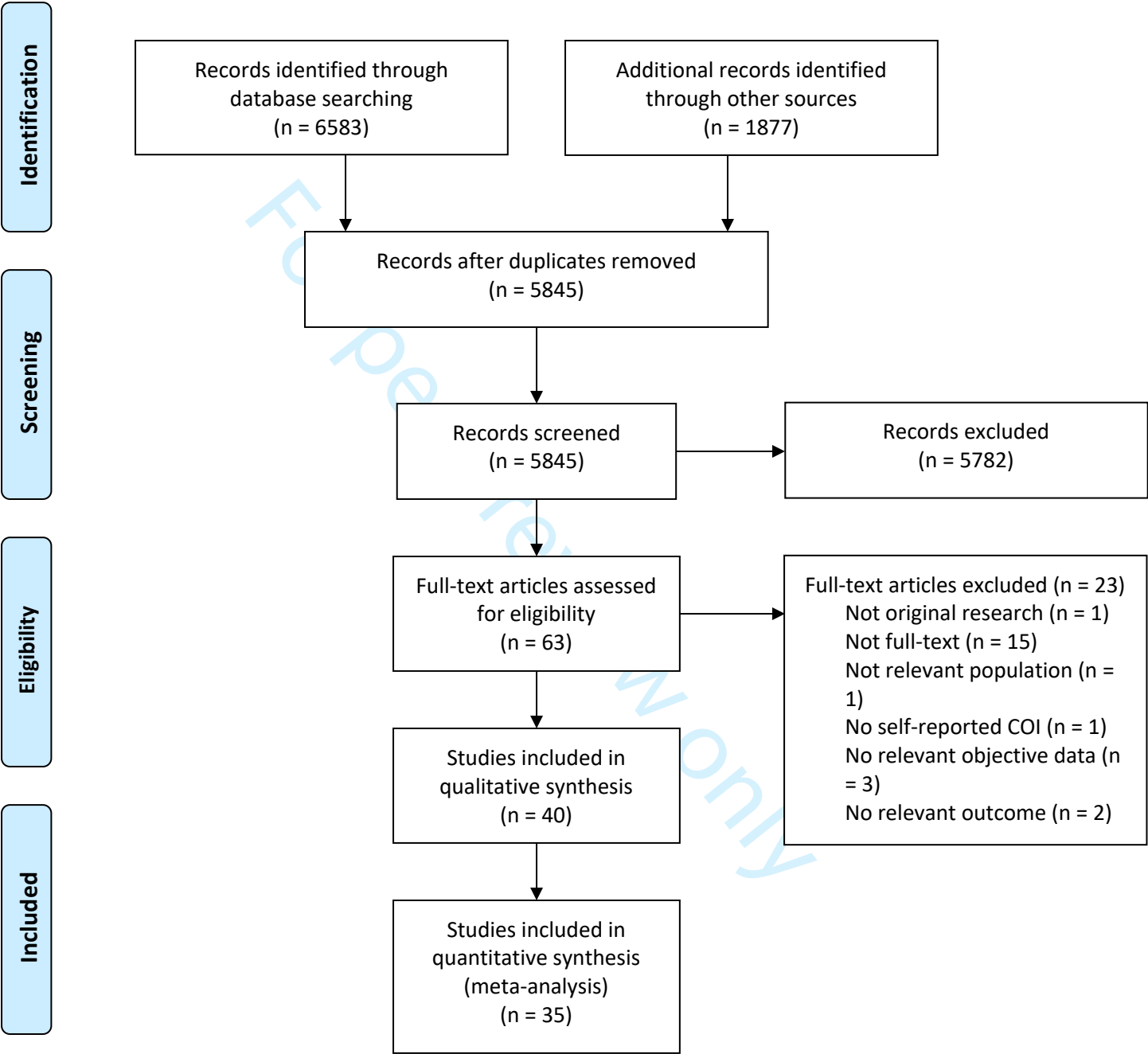
Appendix 1. Search strategy for Medline.

Appendix 2. Forest plot illustrating the number conflicts of interest (COI) discrepancies, defined as the number of unreported COI as a proportion of the total number of conflicts of interest. Panel A represents the COI discrepancies at the article level. Panel B represents the COI discrepancies at the payment level. Panel C represents the COI discrepancies at the authorship level. Panel D represents the COI discrepancies at the author level.

Appendix 3. Forest plot illustrating the reported funding discrepancies, defined as the amount of funding unreported as a proportion of the total funds received.



PRISMA 2009 Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

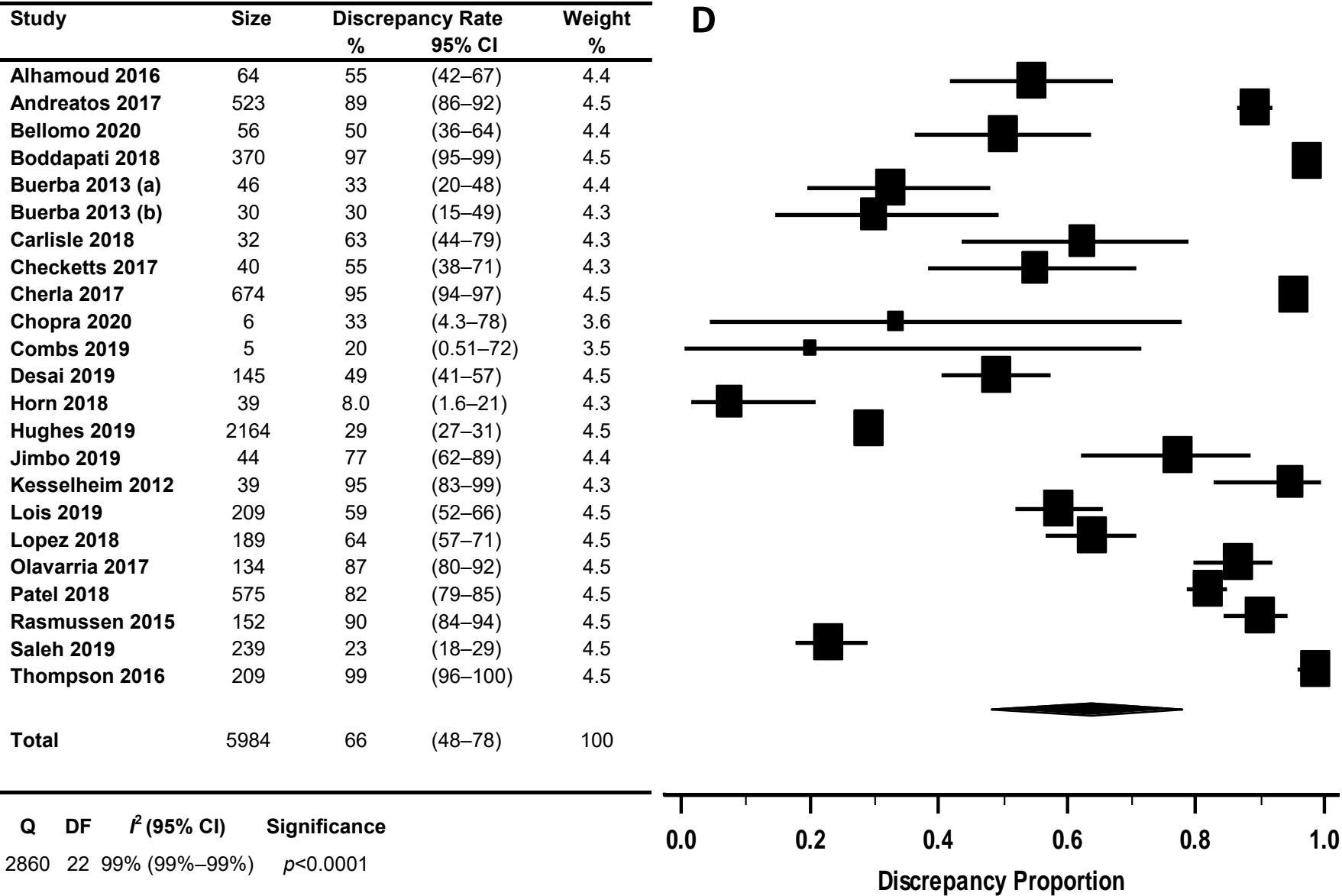
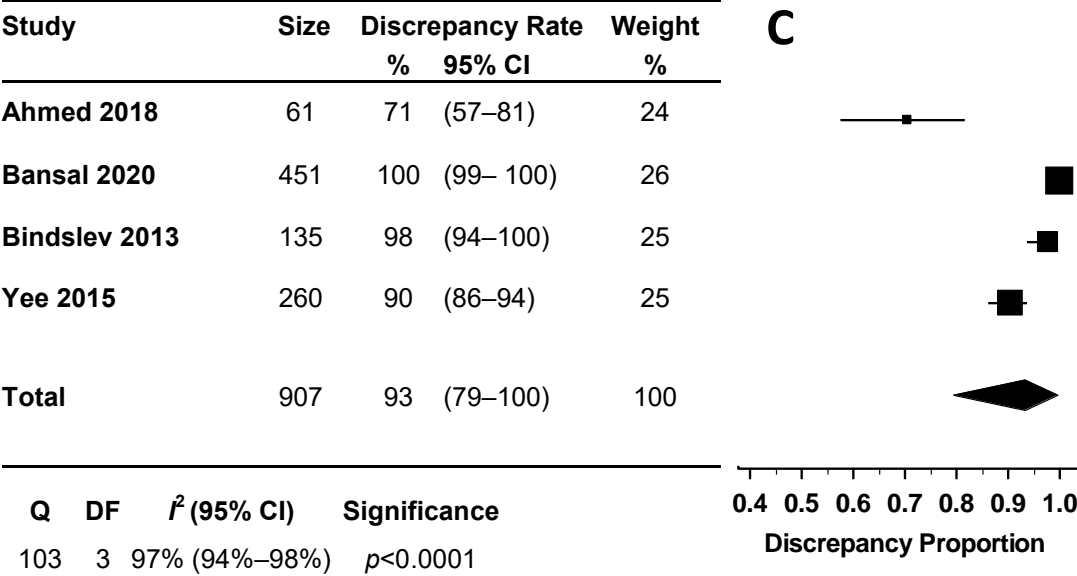
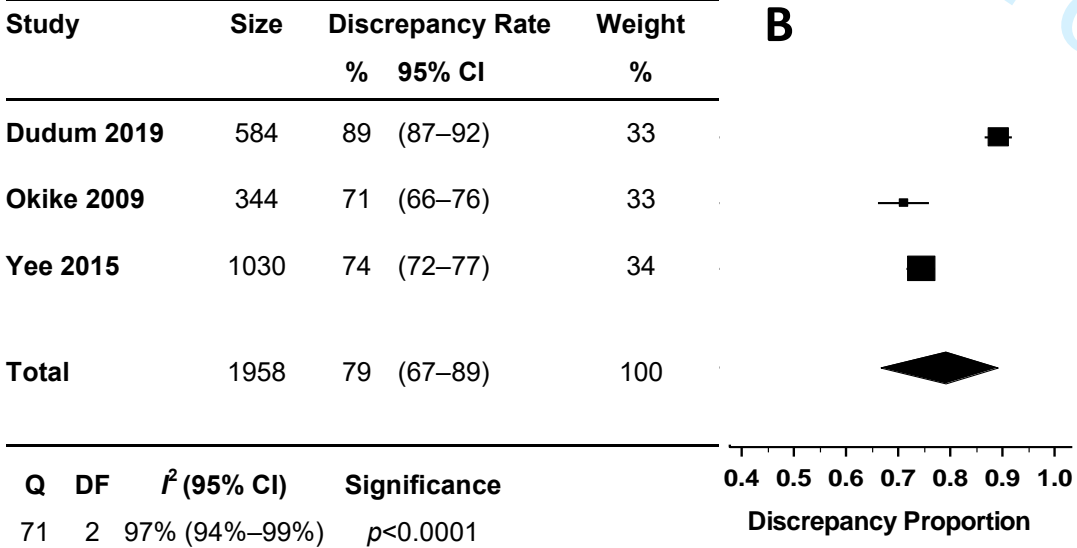
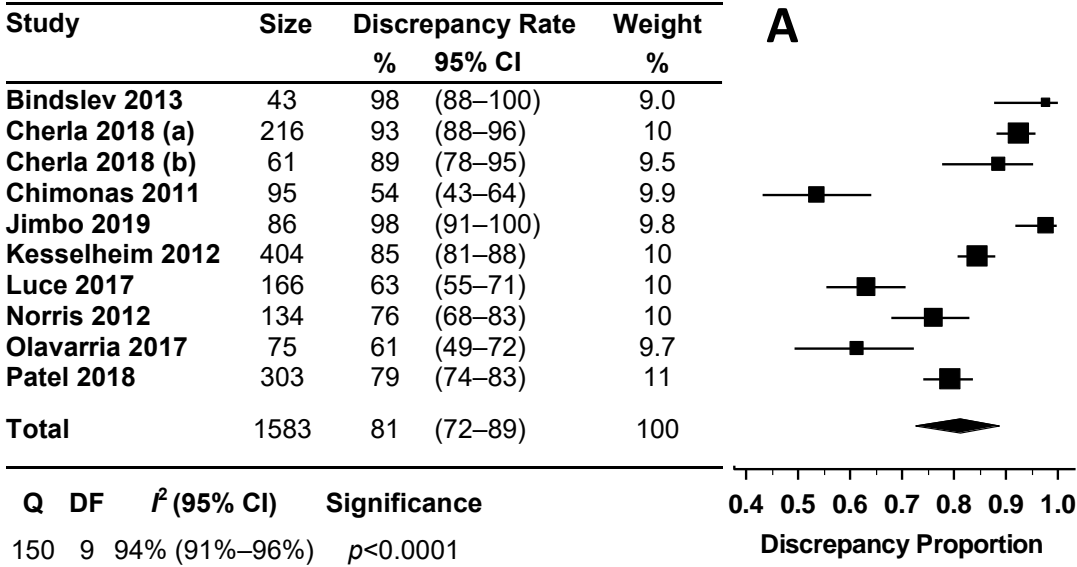
For more information, visit www.prisma-statement.org.

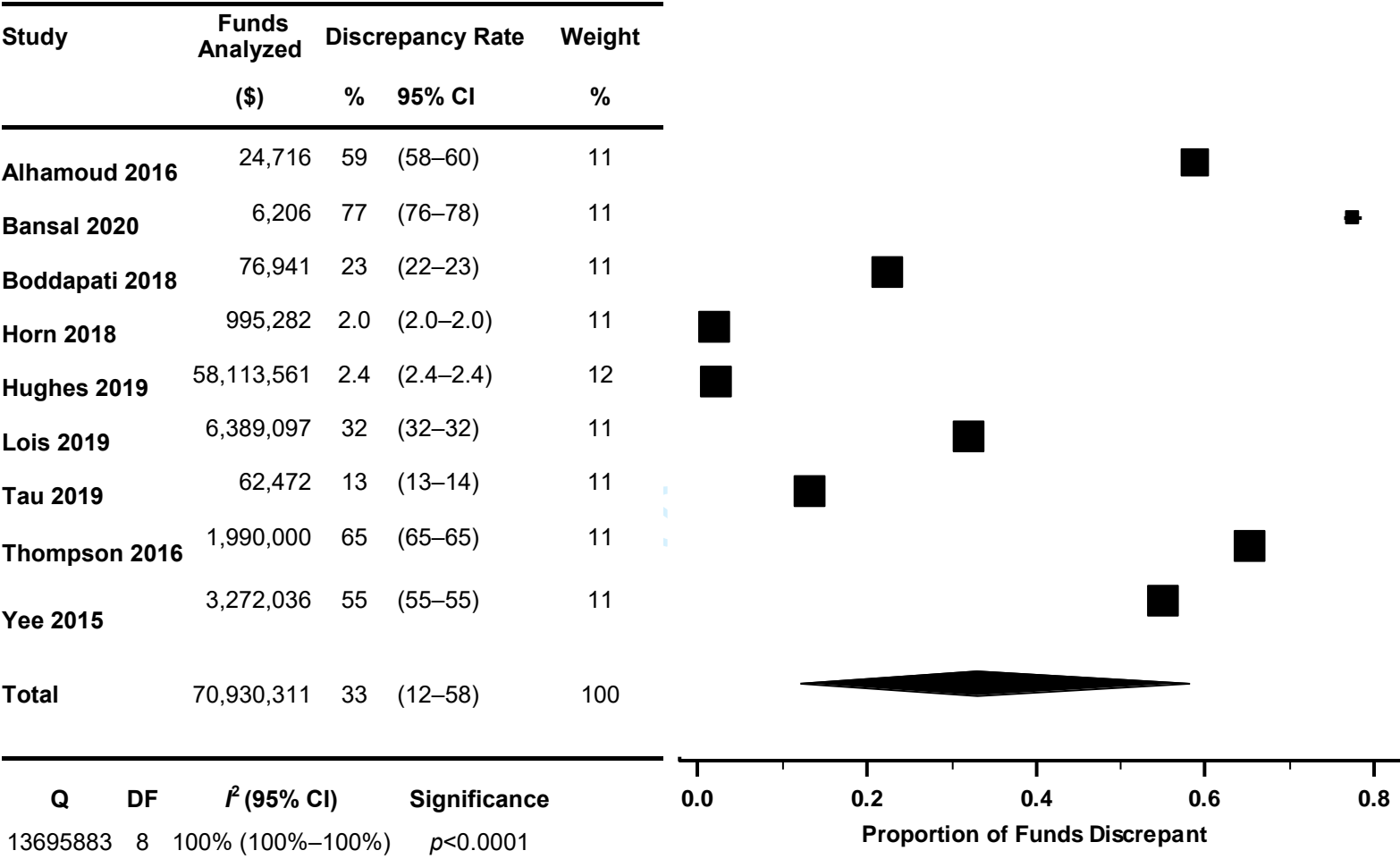
Study	Checklist Item*							
	1	2	3	4	5	6	7	8
Ahmed 2018[22]	+	+	?	+	+	+	+	+
Alhamoud 2016[26]	+	+	?	+	+	+	+	+
Andreatos 2017[33]	+	+	+	+	+	+	+	+
Bansal 2020[34]	+	+	?	+	+	+	+	+
Bellomo 2020[36]	+	+	+	+	+	+	+	+
Bindselev 2013[21]	+	+	?	+	+	+	+	+
Boddapati 2018[35]	+	+	?	+	+	+	+	+
Boyll 2019[51]	+	+	?	+	+	+	+	+
Buerba 2013[14]	+	+	?	+	+	+	+	+
Carlisle 2018[32]	+	+	?	+	+	+	+	+
Cherla 2017[49]	+	+	+	+	+	+	+	+
Cherla 2018a[48]	+	+	+	+	+	+	+	+
Cherla 2018b[50]	+	+	+	+	+	+	+	+
Chimonas 2011[46]	+	+	?	+	+	+	+	+
Chopra 2020[52]	+	+	?	+	+	+	+	+
Combs 2019[30]	+	+	?	+	+	+	+	+
Desai 2019[23]	+	+	?	+	+	+	+	+
Dudum 2019[27]	+	+	?	+	+	+	+	+
Fu 2018[38]	+	+	?	+	+	+	+	+

Garrett-Mayer 2020[55]	+	+	?	+	+	+	+	+
Horn 2018[29]	+	+	?	+	+	+	+	+
Hughes 2019[54]	+	+	+	+	+	+	+	+
Janney 2019[47]	+	+	+	+	+	+	+	+
Jimbo 2019[53]	+	+	?	+	+	+	+	+
Kesselheim 2012[37]	+	+	?	+	+	+	+	+
Lois 2019[25]	+	+	?	+	+	+	+	+
Lopez 2018[15]; U.S.	+	+	+	+	+	+	+	+
Luce 2017[42]; U.S.	+	+	?	+	+	+	+	+
Norris 2012[13]	+	+	+	+	+	+	+	+
Okike 2009[12]	+	+	?	+	+	+	+	+
Olavarria 2017[41]	+	+	+	+	+	+	+	+
Patel 2018[45]	+	+	+	+	+	+	+	+
Rasmussen 2015[20]	+	+	?	+	+	+	+	+
Ross 2020[40]	+	+	?	+	+	+	+	+
Saleh 2019[28]	+	+	?	+	+	+	+	+
Somerson 2020[43]	+	+	?	+	+	+	+	+
Tau 2019[39]	+	+	?	+	+	+	+	+
Thompson 2016[24]	+	+	?	+	+	+	+	+
Yee 2015[44]	+	+	?	+	+	+	+	+

*1. Was the sample frame appropriate to address the target population? 2. Were study participants sampled in an appropriate way? 3. Was the sample size adequate? 4. Were the study subjects and the setting described in detail? 5. Was the data analysis conducted with sufficient coverage of the identified sample? 6. Were valid methods used for the identification of the objective payment data? 7. Were measurements conducted in a standard, reliable way for all participants? 8. Was there appropriate statistical analysis?

#	Searches
1	exp "conflict of interest"/
2	((conflict* or compet* or financial) adj1 (interest* or disclos*)).tw,kf.
3	exp Financial Support/es [Ethics]
4	(allergist* or anesthesiologist* or anesthetist* or cardiologist* or clinician* or dermatologist* or diabetologist* or doctor* or endocrinologist* or gastroenterologist* or general practitioner* or geriatrician* or gynecologist* or haematologist* or hospitalist* or internist* or medical resident* or neonatologist* or nephrologist* or neurologist* or neurosurgeon* or obstetrician* or oncologist* or ophthalmologist* or otolaryngologist* or pathologist* or pediatrician* or physician* or podiatrist* or psychiatrist* or pulmonologist* or radiographer or radiologist* or rheumatologist* or surgeon* or urologist*).tw,kf.
5	1 or 2 or 3
6	4 and 5







PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	22
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	9
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	9
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	22
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	25

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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